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The effects of parenting interventions for at-risk parents with infants: A systematic review and meta-analyses

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015707
Article Type:	Research
Date Submitted by the Author:	27-Dec-2016
Complete List of Authors:	Rayce, Signe; Nationale Forskningscenter for Velfard, Child and Family Rasmussen, Ida ; Nationale Forskningscenter for Velfard, Child and Family Klest, Siu; University of Tromsø, The Regional Centre for Child and Youth Mental Health and Child Welfare - North Patras, Joshua; University of Tromsø, The Regional Centre for Child and Youth Mental Health and Child Welfare - North Pontoppidan, Maiken; Nationale Forskningscenter for Velfard, Child and Family
Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	General practice / Family practice, Paediatrics, Public health
Keywords:	PAEDIATRICS, Community child health < PAEDIATRICS, PRIMARY CARE, Child & adolescent psychiatry < PSYCHIATRY, PUBLIC HEALTH, Clinical trials < THERAPEUTICS

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The effects of parenting interventions for at-risk parents with infants: A systematic review and meta-analyses

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Word count: 4097

Keywords: Child development, infant development, parent-child relationship, parenting intervention, systematic review.

ABSTRACT

Objectives: Infancy is a critical stage of life, and a secure relationship with caring and responsive caregivers is crucial for healthy infant development. Early parenting interventions aim to support families in which infants are at risk of developmental harm. The objective was to systematically review the effects of parenting interventions on child development and on parent–child relationship outcomes for at-risk families with infants aged 0–12 months.

Design: A systematic review and meta-analyses. We extracted publications from 10 databases in June 2013, January 2015, and June 2016, and supplemented with grey and hand search. We assessed risk of bias, calculated effect sizes, and conducted meta-analyses.

Inclusion criteria: 1) Randomized controlled trials of structured psychosocial interventions offered to at-risk families with infants aged 0–12 months in Western OECD countries, 2) Interventions with a minimum of three sessions and at least half of these delivered postnatally, and 3) Outcomes reported for child development or parent–child relationship.

Results: Sixteen studies were included. Meta-analyses were conducted on seven outcomes represented in 13 studies. Parenting interventions significantly improved child behavior ($d=0.14$; 95% CI: 0.03 to 0.26), parent–child relationship ($d=0.44$; 95% CI: 0.09 to 0.80), and maternal sensitivity ($d=0.46$; 95% CI: 0.26 to 0.65) post-intervention. There were no significant effects on cognitive development ($d=0.13$; 95% CI: -0.08 to 0.41), internalizing behavior ($d=0.16$; 95% CI: -0.03 to 0.33), or externalizing behavior ($d=0.16$; 95% CI: -0.01 to 0.30) post-intervention. At long-term follow-up we found no significant effect on child behavior ($d=0.15$; 95% CI: -0.03 to 0.31).

Conclusions: Interventions offered to at-risk families in the first year of the child's life appear to improve child behavior, parent–child relationship, and maternal sensitivity post-intervention, but not child cognitive development, internalizing, or externalizing behavior. Future studies should incorporate follow-up assessments to examine long-term effects of early interventions.

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Strengths and limitations of this study:

- Comprehensive search strategy and screening procedure
- Evaluation of child development and parent–child relationship outcomes
- Meta-analyses conducted on seven outcomes
- Few studies provide follow-up data
- Limited information on implementation

For peer review only

INTRODUCTION

The first year of a child's life is characterized by rapid development that forms the foundation for lifelong developmental trajectories. A healthy environment is crucial for infants' emotional well-being and future physical and mental health.[1,2]

Experiencing severe adversity early in life can alter a child's development and lead to toxic stress responses, impairing brain chemistry and neuronal architecture.[3] For infants, severe adversity typically takes the form of caretaker neglect and physical or emotional abuse. The highest rates of child neglect and violent abuse occur for children younger than five,[4,5] with the most severe cases, which involve injury or death, occurring predominantly to children under the age of one.[6]

Mental health problems are common in infants, but symptoms are often less intrusive and less distinctly identifiable than for older children.[7–12] The Copenhagen Child Cohort study (CCC2000) found a prevalence rate of 18% for axis I diagnoses (according to DC: 0–3) in children aged 18 months, with regulatory disorders and disturbances in parent child–relationships being the most frequent mental health diagnoses.[8] The high prevalence in mental health diagnoses is important to note, as early onset of behavioral or emotional problems and adverse environmental factors increases the risk for negative outcomes later in life, such as substance abuse, delinquency, violence, teen pregnancy, school dropout, continued mental health problems, and long-term unemployment.[1,2,8,13–18]

Becoming a parent can be stressful and challenging,[19–21] particularly for parents who have experienced trauma, abuse, poverty, or other stressors.[3] Early-intervention parenting programs aim to assist parents with the challenges they experience. Most of these interventions teach caretakers specific strategies and skills

that foster healthy child development with an emphasis on promoting warm and responsive caregiving.[22]

Existing systematic reviews of the effects of parenting interventions offered to families with young children have shown mixed results.[14,23–28] In a review of 78 studies aimed at families with children aged 0–5 years, Piquero et al. found an average effect size (*g*) of 0.37 for decreased antisocial behavior and delinquency for intervention children.[14] Based on 22 studies, Barlow et al. concluded that there is tentative support for the effect of group-based interventions on emotional and behavioral adjustment in children aged 0–3 years.[27] Macbeth et al. found medium effect sizes for child or parent outcomes in a review of the Mellow Parenting intervention for families with children aged 0–8 years.[23] Barlow et al. found some evidence suggesting that parenting programs for teenage parents may improve parent–child interaction.[25] Barlow et al. reviewed parent–infant psychotherapy for high-risk families with infants aged 0–24 months; they found that infant attachment improved, but they found no effects on other outcomes.[26] Reviewing interventions offered to a universal group of parents of infants aged 0–1 year, Pontoppidan et al. found mixed and inconclusive results for child development and parent–child relationship outcomes.[24] Peacock et al. examined the effects of home visits for disadvantaged families with children aged 0–6 years and found improved child development outcomes when the intervention was implemented early.[29]

The existing reviews include very few studies of interventions for at-risk parents that are initiated within the first year of the infants’ life. Therefore, we do not know if early preventive parenting interventions are effective in improving child development or parent–child relationship outcomes. The aim of this review was to

systematically review the effects of parenting interventions offered to at-risk families with infants aged 0–12 months. We include randomized controlled trials of parenting interventions reporting child development or parent–child relationship outcomes at post-intervention or follow-up.

METHODS

Search strategy

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We did not register a protocol. The database searches were performed in June 2013 and were updated in January 2015 and June 2016. We searched ten international bibliographic databases: Campbell Library, Cochrane Library, CRD (Centre for Reviews and Dissemination), ERIC, PsycINFO, PubMed, Science Citation Index Expanded, Social Care Online, Social Science Citation Index, and SocIndex. Operational definitions were determined for each database separately. The main search was made up of combinations of the following terms: infant*, neonat*, parent*, mother*, father*, child*, relation*, attach*, behavi*, psychotherap*, therap*, intervention*, train*, interaction, parenting, learning, and education. The searches included Medical Subject Headings (MeSH), Boolean operators, and filters. Publication year was not a restriction. Furthermore, we searched for grey literature, hand searched four journals, and snowballed for relevant references.

Eligibility criteria and study selection

We screened all publications based on title and abstract. Publications that could not be excluded were screened based on the full-text version. Table 1 shows the inclusion and exclusion criteria.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Population	
At-risk population of parents of infants 0-12 months old in western OECD countries	Studies including specific groups such as young mothers (mean age <20 years), divorced parents, parents with mental health problems such as schizophrenia and abuse and children born pre-term, at low birth weight or with congenital diseases.
Intervention	
Structured psychosocial parenting intervention consisting of at least three sessions and initiated either antenatal or during the child's first year of life with at least half of the sessions delivered postnatally.	Interventions not focusing specifically on parenting (e.g. baby massage, reading sessions with child, or breastfeeding interventions), and unstructured interventions (e.g. home visits not offered in a structured format).
Control group	
No restrictions were imposed. All services or comparison interventions received or provided to the control group were allowed.	
Outcome	
Child development and/or parent-child relationship outcomes	Studies reporting only physical development or health outcomes such as height, weight, duration of breastfeeding, and hospitalization. Papers with insufficient quantitative outcome data to generate standardized mean differences (Cohen's d), odds ratios (OR) and confidence intervals (CI).
Design	
Randomized controlled trials (RCT) or quasi-RCTs.	Other study designs such as case control, cohort, cross sectional, and systematic reviews
Publication type	
Studies presented in peer-reviewed journals, dissertations, books or scientific reports.	Abstracts or conference papers. Studies published in languages others than English, German or the Scandinavian languages (Danish, Swedish and Norwegian).

Each publication was screened by two research assistants under close supervision by MP and SBR. Uncertainties regarding inclusion were discussed with MP and SBR. Screening was performed in Eppi-Reviewer 4.

Data extraction and risk of bias assessment

We developed a data extraction tool for the descriptive coding and extracted information on 1) study design, 2) sample characteristics, 3) setting, 4) intervention

1 details, 5) outcome measures, and 6) child age at post-intervention and at follow-up.
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3 Information was extracted by one research assistant and subsequently checked by
4
5 another reviewer. Disagreements were discussed with MP or SBR. Primary outcomes
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7 were child behavior and the parent–child relationship. Secondary outcomes were
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9 other child development markers such as cognitive development,
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11 language/communication, psychomotor development, parent sensitivity, and
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13 attachment classification. When reported, both total scores and subscale scores were
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15 extracted.
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21 Numeric coding of outcome data was conducted by ISR and checked by MP or SBR.
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23 We resolved disagreements by consulting a third reviewer. Risk of bias was assessed
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25 separately for each relevant outcome for all studies based on a risk-of-bias model
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27 developed by Professor Barnaby Reeves and the Cochrane Nonrandomized Studies
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29 Method Group (Reeves, Deeks, Higgins, & Wells, unpublished data, 2011). This
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31 extended model is organized and follows the same steps as the existing risk-of-bias
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33 model presented in the Cochrane Handbook, chapter 8.[30] The assessment was
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35 conducted by ISR and SBR. Any doubts were discussed with a third reviewer.
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40 41 **Analyses**

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43 We calculated effect sizes for all relevant outcomes for which sufficient data was
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45 provided. Effect sizes were reported using standardized mean differences (Cohen's
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47 *d*) with 95% confidence intervals for continuous outcomes. Data included post-
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49 intervention and follow-up means, raw standard deviations, and sample size.
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52 Alternatively, *t*-values, *F*-tests, χ^2 , *p*-values, mean differences, eta-square and β -
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54 coefficients were used. For dichotomous outcomes, we used odds ratios (ORs) with
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95% confidence intervals as the effect size metric when presenting the effects of the individual studies. When used in meta-analyses, ORs were converted to d using the method presented in Chin (2000).[31] The data used to calculate ORs were number of events and sample sizes. We contacted the corresponding author for more information if a paper presented insufficient information regarding numeric outcomes. When available, we used data from adjusted analyses to calculate effect sizes. When using the adjusted mean difference, we used the unadjusted standard deviations in order to be able to compare the effect sizes calculated from unadjusted and adjusted means, respectively. To calculate effect sizes, we used the Practical Meta-Analysis Effect Size Calculator developed by David B. Wilson at George Mason University and provided by the Campbell Collaboration.

Meta-analysis was performed when the intervention outcome and the time of assessment were comparable. If a single study provided more than one relevant measure or only subscales for a given meta-analysis, then the effect sizes of the respective measures were pooled into a combined measure.

Random effects inverse variance weighted mean effect sizes were applied and 95% confidence intervals were reported. Studies with larger sample sizes were therefore given more weight, all else being equal. Due to the relatively small number of studies and an assumption of between-study heterogeneity, we chose a random-effects model using the profile-likelihood estimator as suggested in Cornell 2014.[32] Variation in standardized mean difference that was attributable to heterogeneity was assessed with the I^2 . The estimated variance of the true effect sizes was assessed by

the Tau^2 statistic. When indication of high heterogeneity ($I^2 > 75\%$) was found, sensitivity analyses were conducted, removing one study at a time in order to identify a potential source of heterogeneity. The small number of studies in the respective meta-analyses did not allow for subgroup analyses. Results were summarized for child development (behavior, cognitive development, psychomotor development, and communication/language) and parent-child relationship (relationship, sensitivity, and attachment classification) outcomes for the following assessment times: post-intervention (PI), short-term (ST), mid-term (MT), and long-term (LT) follow-up.

RESULTS

Description of studies

The literature search identified 17,984 articles after the removal of duplicates. A flow diagram for the process of study inclusion is illustrated in figure 1. Nineteen papers representing 16 individual studies were included. Kaminski et al. 2013 represented two trials (LA & Miami) and is handled as two studies when reporting results.[33] Four studies were excluded, as they provided insufficient numeric data to calculate effects sizes and Cis.[34–37] One study was excluded due to unacceptably high risk of bias.[38]

Figure 1 about here

Included studies

Except for one study,[39] which compared a group-based intervention to an individual-based intervention, all studies compared interventions to a no-intervention control or to treatment as usual (TAU) . A few studies offered minor interventions such as psychoeducation and social worker contact to the control group.[40–43] Eight studies were American,[33,39–41,43–45]two were conducted in the Netherlands,[46–48] and one study each was from Sweden,[49–51] Germany,[52] Italy,[53] New Zealand,[54,55] Norway,[42] and the United Kingdom.[56] The oldest study was published in 1981[44] and the most recent studies were published in 2015.[42,49,50,52] Sample size ranged from 40 participants [40] to 755.[52]

Participant characteristics

Table 2 shows study participant characteristics. All families exhibited at least one risk factor such as poverty, low education, or living in deprived areas. Some samples were further characterized by, for example, insecure attachment, risk of developmental delay, or having a difficult or irritable infant. We did not include studies targeting families with more severe problems such as drug abuse, incarceration, or chronic diseases.

Mothers’ mean age ranged from 21–33 years. Four studies recruited primiparous mothers,[41,46–48,52] five studies also included mothers with more than one child, [40,42,43,45,49–51] and seven studies did not report parity.[33,39,44,53–56]

Table 2 Participant characteristics

Study	Country	Risk	Mother mean age at start in years	Child age at start in months	Primiparous %	Intervention, n	Control, n
Ammaniti et al[53]	Italy	Depressive or psychosocial risk	33	Third trimester	Not reported	47	44
Baggett et al[40]	USA	Low income	Intervention: 25; Control: 27	~4	Mean number of children: 1.75	20	20
Barlow et al[56]	UK	Vulnerable	< 17 years: Intervention:17.9%; Control:22.2 %	Second trimester	Not reported	68	63
Bridgeman et al[44]	USA	Low income	17 – 35	3-5	Not reported		Unclear ‡
Cassidy et al[41]	USA	NBAS or low income	24	6.5-9	100	85	84
Fergusson et al[55] & Fergusson et al[54]	New Zealand	Two or more risk factors present	Mother: Intervention: 24; Control: 24 Father: Intervention: 27; Control: 27	Not reported (Recruited within 3 months of birth)	Not reported	206	221
Hoivik et al[42]	Norway	Interactional problems	30	7.3	72	88	70
Kaminski et al[33]	USA	Low income	24	Prenatally (LA), at birth (Miami)	Not reported	338	236
Katz et al[43]	USA	African American with inadequate prenatal care	25	0	Mean number of children: 2.9	146	140
Mendelsohn et al[45]	USA	Low educated latina mothers	Intervention: 30; Control: 30	0.5	Intervention: 21.2; control: 36.2	77	73
Salomonsson et al[51] Salomonsson et al[50] & Salomonsson et al[49]	Sweden	Worried mothers	Intervention: ~34; Control: ~32	Intervention:4.4; Control:5.9	Intervention:81; Control:78	40	40
Sierau et al[52]	Germany	Economic- and social risk factors	Intervention: 21; Control: 22	Third trimester	100	394	361
Taylor et al[39]	USA	Poverty, single marital status, low education, age <20, previous substance abuse, or a history of abuse	Intervention (n): <20: 44, 20-30:122, >30:34; Control: <20:58, 20-30:108, >30:34	3	Not reported	50	50
van den Boom et al[47] & van den Boom et al[46]	Netherlands	Lower-class mothers with irritable infants	Mother: 25 Father: Intervention:28; control:29	6	100	50	50
Velderman et al [48]	Netherlands	Insecure attachment	28	~7	100	54	27

‡ The study only reported number of participants in each analysis

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Interventions

Table 3 presents the intervention details. Nine studies offered individual home visits,[41–43,46–48,52–55,57] three studies combined individual sessions (e.g., home visits) and group sessions,[33,43] three offered individual sessions alone (including web coaching),[40,45,49–51] and two studies offered group sessions.[39,44] Intervention was initiated prenatally in four studies,[33,52,53,56] and 12 studies initiated intervention after the child was born.[33,39–51,54,55] The duration of the interventions varied from relatively short interventions (≤ 6 months) [40,41,46–51] to medium-length interventions (7–12 months) [39,42,43,53,56] to long interventions (≥ 24 months).[33,44,45,52,54,55]

Table 3 Intervention characteristics

Study	Name of intervention	N	Intervention				Control	Outcome	
			Begins	Intensity	Format	Ends/duration		Measure	Child age
Ammaniti et al.[53]	Home Visiting Program (HV)	91	8 months pregnant	Weekly and every second week. ~ 36 sessions	Home visits	Ends: 12 months of age	No intervention	Parent-child relationship	12 months
Baggett et al.[40]	Infant Net	40	3-8 months of age	10 online sessions + 1 read to me session + weekly coach calls	Web - coaching	Duration: 6 months	TAU+provided computer and internet technology	Parent-child relationship	~10 months
Barlow et al.[56]	Intervention based on The Family Partnership Model	131	6 months antenatal	Weekly (mean sessions 41.2)	Home visits	Duration: 18 months	TAU	Parent-child relationship Child development	12 months
Bridgeman et al.[44]	Parent Child Development Center (PCDC)	Uncl ear†	2 months of age	Twice a week for a total of six hours	Center visits (evening meetings)	Ends: 36 months of age	No intervention	Parent-child relationship Child developmentΔ	36 months
Cassidy et al.[41]	Circle of security, home visiting	174	6.5-9 months of age	1 hour every 3 weeks	Home visits	Duration: 3 months	Psychoeducational sessions (3*1 hour)	Parent-child relationshipΔ	12 months
Fergusson et al.[55] & Fergusson et al.[54]	Early Start (2 levels of intensity)	443	Recruited within 3 months of birth	Varied. Low level: up to 2.5 hours per 3 months	Home visits	Duration 36 months	No intervention	Child development	~36 months ~9 years
Høivik et al.[42]	Video feedback, Marte Meo	158	Varies, between 0-24 months of age ~7.3 months of age	8 sessions, 9-13 months (mean 11.5 months)	Home visits	Duration: 9-13 months	TAU + health center nurses if needed	Parent-child relationship Child development	~9-10 months ~15-16 months
Kaminski et al., Los Angeles[33]	Legacy for Children	574	Prenatal in LA	Weekly (2.5 hour) for 3 years in LA	Group sessions+individual sessions	Duration: 3 years in LA	No intervention	Child development	~36 months ~48 months ~60 months
Kaminski et al., Miami [33]	Legacy for Children		At birth in Miami	Weekly (1.5 hour) for 5 years in Miami	Group sessions+individual sessions	Ends: 5 years of age in Miami	No intervention	Child development	~60 months
Katz et al.[43]	Pride in Parenting	286	At birth	Weekly from birth through 4 month and biweekly from 5 to 12	Home visits+groups	Ends: 12 months of age	TAU+monthly contacts from	Child development	12 months

Study	Name of intervention	N	Intervention				Control	Outcome	
			Begins	Intensity	Format	Ends/duration		Measure	Child age
	Program (PIP)			months	sessions		a hospital-based social worker		
Mendelsohn et al.[45]	Video Interaction Project (VIP)	150	2 weeks postpartum	12 sessions (30-45 min. each)	Individual sessions	Ends: 36 months of age	TAU	Child development	33 months
Salomonsson et al.[51], Salomonsson et al[50] & Salomonsson et al[49]	Psychoanalytic treatment	80	Varied: Infants below 1½ years, mean age <6 months	23 session (median), 2-3 hour pr. week	Individual sessions	Duration: Unclear, assumingly 6 months	TAU	Parent-child relationship Child development	4½ years ~11 months ~54 months
Sierau et al[52]	Pro Kind	755	36 gestational weeks (assumingly)	Weekly (first 4 weeks after program intake and 4 weeks after birth), bi-weekly, and monthly (last half year of treatment)	Home visits	Ends: 24 months old (assumingly)	TAU	Parent-child relationship Child development	24 months
Taylor et al[39]	Group well child care (GWCC)	220	3 months of age	7 sessions (45-60 min.) up to 15 months	Coaching in groups	Ends: ~15 months of age	Individual well child care (IWCC)†	Parent-child relationshipΔ Child developmentΔ	~ 15 months
van den Boom et al[47] & van den Boom et al[46]	-	100	6 months of age (baseline 10 days after birth)	1 sessions (2 hours) every 3 weeks for 3 months	Home visits	Ends: 9 months of child's age	No intervention	Parent-child relationship	9 months 12 months 18 months
Velderman et al[48]	1. VIPP 2. VIPP-R	81	~ 7 months of age	4 visits (1.5-3 hours) over 9-12 weeks	Home visits	Duration: 9 to 12 weeks	No intervention	Parent-child relationship	11-13 months 13 months

◇ Not a standardized test
† Two active intervention groups, **no** control group
Δ Outcome(s) not included in meta-analysis
‡ Study only reported number of participants in each analysis

Outcomes

Child development and the parent–child relationship were measured based on parent-report questionnaires, teacher-report questionnaires, structured interviews, and videos. Seven studies reported only child development outcomes,[33,39,43,45,52,54,55] five reported only parent–child relationship outcomes,[40,41,46–48,53] and four reported both.[42,44,49–51,56] Timing of assessment was divided into four assessment times: (1) post-intervention follow-up (immediately after intervention ending), (2) short-term follow-up (less than 6 months after intervention ending), (3) medium-term follow-up (7–12 months after intervention ending), and (4) long-term follow-up (more than 12 months after intervention ending). All studies reported a post-intervention outcome. Two studies reported an outcome at short-term follow-up,[42,46,47] two at medium-term follow-up,[33,47] and four at long-term follow-up.[33,49–51,54,55]

Risk of Bias

The risk of bias assessments are shown in the online table 1 and are divided into child development outcomes and parent-child relationship outcomes. Many studies provided insufficient information for at least two domains, thereby hindering a clear judgment for risk of bias. Risk of bias generally ranged between low and medium. However, three studies had outcomes where one or two domains had a moderate risk of bias.[42–44] Two studies had outcomes with high risk of bias in one domain.[42,44] Based on an overall judgement across risk-of-bias domains, two outcomes (CTBS math and BTBS reading scores) [44] and one study [38] were excluded from the review. The reasons were, on the one hand, high risk of bias in relation to “incomplete data addressed” combined with unclear risk of bias

judgements in all other domains [44], and, on the other hand, the pronounced baseline imbalance not being addressed [38].

The outcomes included in the child development meta-analyses were characterized by low to medium and unclear risk of bias domains, whereas the meta-analyses on parent–child relationship outcomes primarily included outcomes with a relatively low or unclear risk of bias. Two studies represented in the meta-analyses of both child development and parent–child relationship outcomes had domains assessed as having moderate or high risk of bias.[42,44]

Child development outcomes at post-intervention

Table 4 presents the study outcomes for the individual studies.

Table 4 Child development outcomes as reported across studies included in the systematic review

Study	Measure	Assessment	Child age in months	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
PI	Behavior										
Barlow et al. 2007[56]	Total problem score BITSEA	Q	12	55	33.52	38.81	49	35.55	39.63	0.05(-0.33;0.44)	
	Competence BITSEA	Q	12	53	14.06	3.65	43	13.37	3.53	0.19(-0.21;0.60)	
Høivik et al. 2015[42]	Total score ASQ:SE	Q	~9-10	37			27			0.40(-0.10;0.90)	$\beta=7.22$, SD of DV=18.51 ■
Salomonsson et al. 2011[51]	Total score ASQ:SE	Q	~11	38	1.00	0.72	37	1.14	0.70	0.20(-0.26;0.65)	Becker's $\delta=0.25$ (adjusted for baseline ASQ:SE)
Sierau et al. 2015[52]	Internalizing CBCL	Q	24	167	9.51	5.95	159	9.94	5.65	0.07(-0.14;0.29)	
	Externalizing CBCL	Q	24	172	15.93	7.56	164	15.34	7.23	0.08(-0.13;0.29)	
Fergusson et al. 2005[55]	Externalizing ITSEA (short)	Q	~36	207			184			0.19 (-0.01;0.39)	Cohen's d provided in paper
	Internalizing ITSEA (short)	Q	~36	207			184			0.26(0.06;0.47)	Cohen's d provided in paper
	Total problem score ITSEA(50 item)	Q	~36	207			184			0.24(0.04; 0.44)	Cohen's d provided in paper
Kaminski et al. 2013, LA[33]	DECA Behavioral concerns	Q	36	126			78			-0.12(-.48;0.25) ✕	OR=0.81 (0.42;1.56)
	DECA Socioemotional problems	Q	36	127			79			-0.04(-0.49;0.43) ✕	OR=0.93(0.41;2.17)
Kaminski et al. 2013, Miami[33]	DECA Behavioral concerns	Q	60	121			73			0.32(-0.07;0.7) ✕	OR=1.78(0.88;3.57)
	DECA Socioemotional problems	Q	60	122			73			0.00(-0.48;0.49) ✕	OR=1.00(0.42;2.44)
	SDQ Conduct problems	Q	60	122			73			0.18(-0.14;0.52) ✕	OR=1.39(0.77; 2.56)
	SDQ Hyperactivity _i	Q	60	121			73			0.31(-0.21;0.84) ✕	OR=1.75(0.69;4.55)
	SDQ Peer problems	Q	60	121			73			-0.14(-.52;0.24) ✕	OR=0.78(0.39;1.54)
Mendelsohn et al. 2007[45]	Total problem score CBCL	Q	33	52	50.2	10.0	47	53.2	9.7	0.30(-0.09; 0.70)	
	Externalizing CBCL	Q	33	52	50.0	9.8	47	51.8	9.4	0.19(-0.21;0.58)	
	Internalizing CBCL	Q	33	52	52.9	9.9	47	53.8	9.3	0.09(-0.30;0.49)	
Katz et al. 2011[43]	BRS	O	12	73			51			0.83(-0.43;2.09) ✕	Normal/non-optimal: Intervention:72/1, control: 48/3, OR=4.5 (0.45; 44.5)
Barlow et al. 2007[56]	BRS	O	12	62	38.37	5.71	59	38.69	5.5	-0.06(-0.41;0.30)	
Sierau et al. 2015[52]	BRS	O	24	160	53.10	26.74	142	57.13	27.79	-0.15(-0.37;0.08)	
PI	Cognitive development										
Barlow et al. 2007[56]	MDI	O	12	62	93.74	10.98	59	93.03	10.89	0.06(-0.29;0.42)	
Katz et al. 2011 [43]	MDI	O	12	73	101.0	12.4	51	101.4	17.3	-0.03(-0.39;0.33)	
Taylor et al. 1997[39]	MDI	O	~15	50	99.3	14.8	50	100.4	14.3	-0.08(-0.47;0.32) ▲	
Sierau et al. 2015[52]	MDI	O	24	180	87.37	14.74	167	87.64	14.74	-0.02(-0.23;0.19)	
Bridgeman et al. 1981, New Orleans, Louisiana[44]	Intelligence Stanford-Binet	O	36	46	104.22	10.36	52	96.69	12.20	0.66(0.25;1.07)	R=0.49 (incl.all independent variables)
	Concept attainment CFI	O	36	38	33.39	4.69	43	28.02	7.01	0.89(0.43;1.35)	
	Perception Pacific test series	O	36	32	32.09	5.29	42	30.00	6.86	0.34(-0.13;0.80)	
Mendelsohn et al. 2007[45]	MDI	O	33	52	86.1	7.5	45	83.9	9.7	0.26(-0.14;0.66)	
PI	Psychomotor development										

Study	Measure	Assessment	Child age in months	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
Katz et al. 2011[43]	PDI	O	12	73	95.1	13.6	51	93.1	11.9	0.15(-0.20;0.51)	
Taylor et al. 1997[39]	PDI	O	~15	50	103.6	11.5	50	100	12.4	0.30(-0.09;0.70) ▲	
Sierau et al. 2015[52]	PDI	O	24	180	92.86	15.08	167	92.81	14.10	0.00(-0.21;0.21)	
PI	Communication/language										
Bridgeman et al. 1981, New Orleans, Louisiana[44]	Ammons	O	36	34	13.44	3.38	38	11.11	3.09	0.72(0.24;1.20)	
Mendelsohn et al. 2007[45]	PLS-3	O	33	52	80.7	10.2	45	81.1	10.6	-0.04(-0.44;0.36)	
Sierau et al. 2015[52]	ELFRA	O	24	169	102.64	64.69	161	107.84	66.63	-0.08(-0.30;0.14)	
	SETK-2	O	24	141	0.78	0.58	128	0.80	0.61	-0.03(-0.27;0.21)	
SF	Behavior										
Høivik et al. 2015[42]	ASQ:SE	Q	~15-16	26			27			1.05(0.47;1.62)	β=-13.79, SD of DV=15.02 ■
MF	Behavior										
Kaminski et al. 2013 LA[33]	DECA Behavioral concerns	Q	48	124			78			0.26(-0.14;0.66) ✕	OR=1.61(0.78;333)
	DECA Socioemotional problems	Q	48	124			78			0.00(-0.55;0.55) ✕	OR=1.00(0.37; 2.70)
	SDQ Conduct problems	Q	48	124			78			0.18(-0.14;0.51) ✕	OR=1.39 (0.77;2.5)
	SDQ Hyperactivity _i	Q	48	124			78			-0.37(-.01;0.26) ✕	OR=0.51(0.16;1.61)
	SDQ Peer problems	Q	48	124			78			-0.12(-.49;0.26) ✕	OR=0.81 (0.41;1.61)
LF	Behavior										
Fergusson et al. 2013[54]	SDQ ○	Q	~108	199	9.91	0.91	171	10.08	1.06	0.17(-0.034; 0.38)	
Kaminski et al. 2013 LA[33]	DECA Behavioral concerns	Q	60	116			71			0.27(-0.21;0.72) ✕	OR=1.62 (0.69;3.70)
	DECA Socioemotional problems	Q	60	117			73			0.49(0.05;1.01) ✕	OR=2.44 (1.10;6.25)
	SDQ Conduct problems	Q	60	116			71			-0.03(-.39;0.33) ✕	OR=0.94 (0.49;1.82)
	SDQ Hyperactivity _i	Q	60	116			71			0.17(-0.37;0.7) ✕	OR=1.35(0.51;3.57)
	SDQ Peer problems	Q	60	116			71			0.17(-0.24;0.58) ✕	OR=1.37(0.65;2.86)
Salomonsson et al 2015a[50]	ASQ:SE	Q	54	32	0.98	0.90	32	0.88	0.68	0.13(-0.37; 0.62)	
	SDQ	Q _{parent}	54	32	8.17	5.54	31	7.39	5.19	0.15(-0.35;0.64)	
	SDQ	Q _{teacher}	54	24	5.71	4.32	27	6.59	5.31	-0.18(-0.73; 0.37)	
	CGAS Functioning	Q	54	31	78.39	12.8	30	68.87	14.74	0.69(0.17; 1.21)	

✕ Calculation based on dichotomous outcome
○ Reverse scoring – high score is negative
■ Adjusted for ASQ baseline score
▲ No control group. Two interventions were compared.
U, unadjusted; Q, questionnaire; O, observation; PI, post-intervention; SF, short-term follow-up (≤6 months post intervention); MF, mid-term follow-up (7-12 months); LF, long-term follow-up (>12 months post-intervention); BITSEA, Brief Infant Toddler Social Emotional Assessment; ASQ:SE, Ages & Stages Questionnaires: Social-Emotional; CBCL, Child Behavior Checklist; ITSEA, Infant Toddler Social Emotional Assessment; DECA, Devereux Early Childhood Assessment; MDI, Mental Developmental Index; PDI, Psychomotor Development Index; CFI, Concept Familiarity Index; PLS-3, Preschool Language Scale; SDQ, Strengths and Difficulties Questionnaires; CGAS, Children's Global Assessment Scale

Meta-analysis of the primary outcome is reported in figure 2, secondary outcomes in online figures.

Figure 2 about here

Behavior

The meta-analysis of parent-reported child behavior shown in figure 2 included eight studies.[33,42,45,51,52,54,56] The analysis showed a small but significant effect on child behavior ($d=0.14$; 95% CI: 0.026 to 0.26) favoring the intervention group. One study that offered a considerably longer intervention than the rest was removed for a sensitivity analysis, which found that the results were not substantially affected by removing the study.[33] The study was therefore kept in the analysis. For the internalizing and externalizing subscales, no significant difference between intervention and control group was found (see online figure 1 and 2). None of the behavioral outcomes that were not included in a meta-analysis showed significant differences between intervention and control group.[43,52,56]

Three studies reported observer-rated child behavior using the behavioral rating scale (BRS) from Bayley II.[43,52,56] One study used a dichotomized version of BRS,[43] which may not have been able to detect changes in this population since all but one (intervention) and three (control) children were rated as unproblematic. Meta-analysis was therefore not conducted. None of the studies found significant effects.

Cognitive development

The meta-analysis on cognitive development included five studies (online figure 3).[43–45,52,58] There was no significant difference between intervention and control groups ($d=0.13$; 95% CI: -0.08 to 0.41). A sensitivity analysis was conducted in which the one study that did not apply the MDI was removed, [44] and the analysis found that the effect size decreased ($d=0.03$) but remained insignificant (95% CI: -0.12 to 0.21).

Psychomotor development

We could not perform meta-analysis for psychomotor development outcomes, as one study provided data comparing two active interventions.[39] Of the three studies that included psychomotor development, none of them found significant effects.[39,43,52]

Communication/language development

We could not perform meta-analysis for communication/language outcomes, as the measures varied considerably. Two studies found no significant effect on communication/language development,[45,52] whereas one found significantly improved communication/language development for the intervention group ($d=0.72$; 95% CI: 0.24 to 1.20).[44]

Child development outcomes at follow-up

Because few studies reported child development outcomes at follow-up, we were only able to conduct a meta-analysis for one of the follow-up outcomes.

Child behavior

1 The meta-analysis of parent-rated child behavior at long-term follow-up, as shown in
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3 online figure 4, included child behavior scores (SDQ) from three studies.[33,50,54]
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5 No significant effect was found ($d=0.15$; 95% CI: -0.03 to 0.31).
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9 At short-term follow-up, one study found a significant positive effect on child
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11 behavior ($d=1.046$; 95% CI: 0.47 to 1.62).[42] At medium-term follow-up, one study
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13 found no significant effects on behavioral concerns, conduct problems, hyperactivity,
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15 or peer problems.[33] At long-term follow-up, one study found a significant positive
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17 effect on child functioning (CGAS) ($d=0.69$; 95% CI: 0.17 to 1.20),[50] and one
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19 study found a significant positive effect on child behavior (DECA) (OR=2.44; 95%
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21 CI: 1.10 to 6.25).[33]
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25 No studies reported follow-up data on cognitive development,
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27 communication/language, or psychomotor development.
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30 **Parent–child relationship at post-intervention**

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32 Table 5 presents the study outcomes for the individual studies.
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Table 5 Parent-child relationship outcomes as reported across studies included in the systematic review

Study	Measure	Assess ment	Child age (months)	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
PI	Maternal sensitivity										
Ammaniti et al. 2006[53]	Sensitivity (M) Homemade	V	12	45	7.25	1.06	37	6.67	1.31	0.49(0.05;0.93)	
Barlow et al. 2007[56]	Sensitivity (M) CARE-index	V	12	62	9.27	2.67	59	8.2	3.26	0.36(0.00;0.72)	
Bridgeman et al. 1981, New Orleans, Louisiana[44]	Sensitivity (M) Ainsworth's rating scale	V	36	42	6.29	1.62	31	5.19	2.30	0.57(0.09;1.04)	
Salomonsson et al 2015b[49]	Sensitivity (M) EAS	V	~11	38	0.64	0.13	37	0.57	0.17	0.46(0.00;0.92)	
Velderman et al. 2006[48]	Sensitivity (M) Ainsworth's rating scale	V	11-13	54			27			0.48(0.02;0.95)	◇
PI	Parent-child relationship										
Ammaniti et al. 2006[53]	Sensitivity (M) (homemade)	V	12	45	7.25	1.06	37	6.67	1.31	0.49(0.05;0.93)	
	Cooperation (D) (homemade)	V	12	45	8.11	0.94	37	7.67	1.19	0.42(-0.02;0.85)	
	Interference (M) (homemade) ○	V	12	45	1.36	0.81	37	1.52	0.80	0.20(-0.24;0.63)	
	Affective state (M) (homemade) ○	V	12	45	1.15	0.44	37	1.39	0.66	0.44(-0.00;0.88)	
	Self-regulative behaviors (C) (homemade)	V	12	45	1.92	0.95	37	1.96	0.99	-0.04(-0.48;0.39)	
Baggett et al. 2010[40]	Positive behaviors (C) Landry	V	~10	20			20			0.69(0.05;1.33)	Eta ² =0.107
	Positive behaviors (P) Landry	V	~10	20			20			0.45(-0.17;1.08)	Eta ² =0.049
Barlow et al. 2007[56]	Sensitivity (M) CARE-index	V	12	62	9.27	2.67	59	8.2	3.26	0.36(0.00; 0.72)	
	Cooperativeness (C) CARE-index	V	12	62	9.35	3.08	59	7.92	3.7	0.42(0.06;0.78)	
Bridgeman et al. 1981, New Orleans, Louisiana[44]	Positive Language (M) Homemade	V	36	42	30.26	27.07	31	7.24	39.93	0.70(0.22;1.17)	
	Sensitivity (M) Ainsworth's rating scale	V	36	42	6.29	1.62	31	5.19	2.30	0.57(0.09;1.04)	
	Acceptance (M) Ainsworth's rating scale	V	36	42	6.87	1.31	31	6.52	1.55	0.25(-0.22;0.71)	
	Cooperation (M) Ainsworth's rating scale	V	36	42	6.03	1.96	31	5.48	1.98	0.28(-0.19;0.75)	
Høivik et al. 2015[42]	EAS ○	V	~9-10	73	151.90	19.6	52	145.84	29.24	0.25(-0.11;0.61)	
Salomonsson et al 2015b[49]	Sensitivity (M) EAS	V	~11	38	0.64	0.13	37	0.57	0.17	0.46(0.00;0.92)	
	Structuring (M) EAS	V	~11	38	0.71	0.12	37	0.68	0.16	0.21(-0.24;0.67)	
	No intrusiveness (M) EAS	V	~11	38	0.78	0.16	37	0.73	0.23	0.25(-0.20;0.71)	
	Responsiveness (C) EAS	V	~11	38	0.70	0.13	37	0.67	0.20	0.18(-0.28;0.63)	
	Involvement (C) EAS	V	~11	38	0.69	0.14	37	0.66	0.19	0.18(-0.27;0.63)	
van den Boom et al. 1994[47]	Interactive behavior (M) (homemade)	V	9	~47			~47			1.78(1.30;2.26)	
	Interactive behavior (C) (homemade)	V	9	~47			~48			1.54(1.08;2.00)	
Sierau et al. 2015[52]	Affectivity (D) MBRS-R	V	24	146	3.16	0.61	142	3.35	0.63	-0.31(-0.54; -0.07)	
	Responsiveness (D) MBRS-R	V	24	145	3.38	0.70	140	3.54	0.68	-0.23(-0.46;0.00)	
Taylor et al. 1997[39]	NCATS	V	~15	50	59.5	6.1	50	59.4	6.0	0.00(-0.39;0.39)▲	

Study	Measure	Assessment	Child age (months)	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
SF	Parent-child relationship										
Høivik et al. 2005[42]	EAS ^o	V	~15-16	63	153.40	22.33	47	156.15	19.25	0.13(-0.25;0.51)	
MF	Parent-child relationship										
van den Boom et al. 1995[46]	Acceptance (M) Based on Ainsworth	V	18	43	6.86	1.19	39	5.95	1.88	0.58(0.14;1.03)	$F=7.04$
	Accessibility (M) Based on Ainsworth	V	18	43	6.88	1.50	39	5.87	1.89	0.60(0.15;1.04)	$F=7.26$
	Cooperation (M) Based on Ainsworth	V	18	43	6.70	1.68	39	5.18	1.65	0.91(0.46;1.37)	$F=16.92$
	Sensitivity (M) Based on Ainsworth	V	18	43	6.70	1.42	39	5.26	1.92	0.86(0.41;1.31)	$F=15.14$
LF	Parent-child relationship										
Salomonsson et al 2015b[49]	Sensitivity (M) EAS	V	54	33	0.68	0.12	33	0.67	0.16	0.07(-0.41;0.55)	
	Structuring (M) EAS	V	54	33	0.66	0.12	33	0.69	0.13	-0.24(-0.72;0.24)	
	No Intrusiveness (M) EAS	V	54	33	0.82	0.12	33	0.81	0.14	0.08(-0.406;0.56)	
	Responsiveness (C) EAS	V	54	33	0.69	0.19	33	0.74	0.15	-0.29(-0.78;0.19)	
	Involvement (C) EAS	V	54	33	0.67	0.13	33	0.72	0.16	-0.34(-0.83;0.14)	
PI	Attachment										
Cassidy et al. 2011[41]	Attachment SSP	V	12	85			84			0.30(-0.06;0.66) Δ	$B=0.54$ (SE=0.33) $OR=1.72(0.90;3.28)$ \square
Velderman et al. 2006[48]	Attachment SSP	V	13	54			27			0.22(-0.22;0.66)	
SF	Attachment										
van den Boom et al. 1994	Attachment SSP	V	12	50			50			0.97(0.48;1.45) Δ	Secure/insecure: Intervention: 31/9, control: 11/39. $OR=5.78$ (2.40;13.94). $L^2(1)=16.96$
MF	Attachment										
van den Boom et al. 1995[46]	Attachment SSP	V	18	43			39			1.07(0.58;1.57) Δ	$\chi^2=18.35$
LF	Attachment										
Salomonsson et al 2015a[50]	Secure Attachment SSAP	V	54	31	2.22	1.05	30	2.32	1.33	-0.08(-0.59;0.42)	
	Avoidant Attachment SSAP ^o	V	54	31	1.05	0.48	30	1.16	0.52	0.22(-0.28;0.72)	
	Ambivalent Attachment SSAP ^o	V	54	31	0.96	0.73	30	0.84	0.61	-0.18(-0.68;0.32)	
	Disorganized Attachment SSAP ^o	V	54	31	0.80	0.84	30	0.63	0.58	-0.23(-0.74;0.27)	

Δ Calculation based on dichotomous outcome

^o Reverse scoring – high score is negative

\diamond Adjusted for pretest sensitivity

\square Adjusted for income, infant sex and irritability

\blacktriangle No control group. Two interventions were compared.

U, unadjusted; Q, questionnaire; O, observation; V, video; M, mother; C, child; PI, post-intervention; SF, short-term follow-up (≤ 6 months post intervention); MF, mid-term follow-up (7-12 months); LF, long-term follow-up (> 12 months post-intervention); NOLA, New Orleans Louisiana; CARE, Child-Adult Relationship Experimental; EAS, Emotional Availability Scales; NCATS, Nursing Child Assessment Teaching Scale; SSP, Strange Situation Procedure; SSAP, Story Stem Assessment Profile

Meta-analysis of the primary outcome is reported in figure 3, secondary outcomes in online figures.

Figure 3 about here

Parent–child relationship

The meta-analysis of the overall parent–child relationship included nine studies and is presented in figure 3.[40,42,44,47–49,52,53,56] The parent–child relationship was significantly better in the intervention group as compared to the control group ($d=0.44$; 95% CI: 0.09 to 0.80). The measures reported in the studies vary to some degree, which could be a source of heterogeneity. I^2 was 80.88, indicating that a large proportion of the observed variance in effect sizes may be attributable to heterogeneity rather than to sampling error.

Maternal sensitivity

We performed a separate meta-analysis on maternal sensitivity, which is a central component in the parent–child relationship. The meta-analysis included five studies (online figure 5) and showed a significant effect favoring the intervention group ($d=0.46$; 95% CI: 0.26 to 0.65).[44,48,49,53,56]

Attachment

Two studies reported attachment classification.[41,48] They found no significant effects of the intervention.

Parent–child relationship at follow-up

Because few studies reported parent–child relationship outcomes at follow-up, we could not conduct meta-analyses for any parent–child relationship follow-up outcomes.

At short-term follow-up, one study found no significant effect on the parent–child relationship.[42] At medium-term follow-up, one study found significant positive effects on maternal acceptance ($d=0.58$; 95% CI: 0.14 to 1.03), accessibility ($d=0.60$; 95% CI: 0.15 to 1.04), and cooperation ($d=0.91$; 95% CI: 0.46 to 1.37).[46] At long-term follow-up, one study did not find a significant effect on the parent–child relationship.[49]

Maternal sensitivity

At medium-term follow-up, one study found a significant positive effect on maternal sensitivity ($d=0.86$; 95% CI: 0.41 to 1.31).[46] At long-term follow-up, one study found no significant effect on maternal sensitivity.[49]

Attachment

At short- and medium-term follow-up, one study found a significant positive effect on attachment at both the 12-month follow-up ($d=0.97$; 95% CI: 0.48 to 1.45) and the 18-month follow-up ($d=1.07$; 95% CI: 0.58 to 1.57).[46,47] At long-term follow up, one study did not find a significant effect on attachment.[50]

Sensitivity analyses

The meta-analysis on the parent–child relationship indicated that substantial heterogeneity may be present. Sensitivity analyses showed that one study in particular contributed to the high I^2 -value.[47] When this study was removed from

the analysis, I^2 and Tau^2 decreased to 47.11 and 0.04 (95% CI: 0.00 to 0.22), respectively. The effect size decreased to 0.26 (95% CI: 0.05 to 0.50).

Two of the studies included in the meta-analyses had outcomes with domains at moderate to high risk of bias.[42,44] Removing Bridgeman et al. (1981) from the meta-analysis on child behavior did not alter the results considerably ($d=0.12$; 95% CI: 0.01 to 0.25). When removed from the analysis on cognitive development, the effect decreased but remained insignificant ($d=0.032$; 95% CI: -0.03 to 0.21). For the parent–child relationship the effect was almost unchanged when Bridgeman et al. (1981) and Høivik et al. (2015) were removed. The effect did, however, approach insignificance ($d=0.47$; 95% CI: 0.00 to 0.95). The effect on maternal sensitivity ($d=0.44$; 95% CI: 0.22 to 0.65) was not altered considerably by removing Bridgeman et al. (1981).

Relative effects

One study compared two active interventions: group and individual.[39] The authors found no difference between the two interventions on cognitive development, psychomotor development, or the parent–child relationship.

DISCUSSION

We identified 19 papers representing 16 trials that investigated the effects of parenting interventions delivered to at-risk parents of infants aged 0–12 months. Due to the variety of outcome measures applied, not all of the 16 included studies were included in the meta-analyses. At post-intervention, we found a small but significant positive effect on overall child behavior, but no significant effects on child cognitive behavior or the child behavior subscales internalizing or externalizing. We found a

1 medium-sized effect on overall parent–child relationship and maternal sensitivity.
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3 Most of the findings from studies that were not represented in the meta-analyses
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5 were not statistically significant.
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9 The meta-analyses showed the most pronounced effect sizes for parent–child
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11 interaction and maternal sensitivity, whereas the effects on child behavior and
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13 cognitive development were either small or not significant. Most interventions
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15 provided direct support for how to improve maternal sensitivity and the relationship
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17 between parent and child (e.g., Circle of Security [59] and VIPP [60]). Therefore, it
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19 seems reasonable that the parent–child relationship and maternal sensitivity can be
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21 improved within a relatively short time period, whereas the effects of the
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23 interventions on child development may take longer to emerge.[61]
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28 Two studies represented in the meta-analyses were assessed as having a moderate to
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30 high risk of bias in one [44] or two [42] domains. As this could potentially affect the
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32 credibility of the results, we conducted sensitivity analyses to investigate these
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34 studies' contribution to the effect sizes. However, removing these studies from the
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36 analyses did not substantially alter the effects.
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40 The number of studies in the meta-analyses ranged from three to nine. While a meta-
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42 analysis on nine studies is fairly reliable, a meta-analysis including only three studies
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44 may provide a less accurate estimate of the overall effect.[62] We therefore applied
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46 the random-effects model using the profile-likelihood estimator. This has been
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48 recommended for meta-analyses with a small number of studies, because it generates
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50 wider confidence intervals than the frequently applied DerSimonian-Laird
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52 estimator.[32] The results of the meta-analyses including fewer studies should still be
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54 interpreted with some caution.
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This review focuses on interventions for adult mothers; studies with young mothers were excluded, including central studies such as the Olds studies of Nurse Family Partnership (NFP).[61] Although teen mothers are an at-risk group, especially since they often face other risk factors such as poverty, low education, and single parenthood, we have not included them in this review. This is mainly because teen mothers are not yet fully developed. We consider the narrower focus on adult mothers to be a strength, because interventions aimed at teen mothers often differ considerably from interventions aimed at adult mothers.

The included studies were conducted in countries with different levels of service for families with infants; therefore, it may not be possible to reproduce effects in other contexts. The interventions examined in the studies also varied according to approach, intensity, and duration. Both short and extensive interventions were included in all meta-analyses, and we found no apparent tendencies in the results. Due to the relatively low number of studies in the meta-analyses, we could not conduct subgroup analyses. Subgroup analyses are important as they provide information about whether the effect of an intervention is modified by certain circumstances or characteristics of the participants. Eight of the included studies reported some kind of subgroup or moderator analyses.[41–45,47,48,53]

Most of the studies did not address implementation in their design. This presents challenges with regard to assessing outcomes, as results may have been moderated, both positively and negatively, by implementation quality. Of the 16 studies reviewed, four provided information about efforts to support implementation, such as strategies to reduce participant attrition,[43] information about variability in the number of intervention sessions that some families received,[40,43,52] and

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information on the intervention.[46,47,52] All of the studies could have included more information about the implementation context and the possible moderating factors associated with different strategies. Without more extensive implementation information, replicability remains problematic, particularly in circumstances where implementation supports were not well documented.

A further limitation of the study is that although many studies reported outcomes during the intervention period and post-intervention, only a few reported follow-up data. We were able to perform meta-analysis for one long-term outcome: child behavior measured by the SDQ. The analysis included three studies and found no significant difference between intervention and control groups. Individual study results at different follow-up times were mixed and therefore inconclusive for both child development and the parent–child relationship at long-term follow-up. It is problematic that the studies did not assess long-term outcomes, because it makes it impossible to evaluate the short-, medium-, and long-term effects of the interventions. Conclusions based on post-intervention assessments may be insufficient to draw firm conclusions about the effectiveness of parenting interventions.

CONCLUSION

This review identified 16 studies that evaluated the effects of parenting interventions for at-risk caregivers with infants aged 0–12 months on child development and the parent–child relationship. Meta-analyses revealed a small but significant effect on child behavior as well as moderate effects on the parent–child relationship and maternal sensitivity. There were no effects on cognitive development, internalizing

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behavior, or externalizing behavior at post-intervention, nor were any effects found on child behavior at long-term follow-up. Parenting interventions initiated in the child’s first year of life seem to have the potential to improve child behavior and the parent–child relationship post-intervention.

Few studies assessed child development and parent-child relationship outcomes at follow-up; therefore, it remains unclear whether parenting interventions delivered in this population will have lasting effects. Future studies should incorporate follow-up assessments to examine the long-term effects of early interventions.

ACKNOWLEDGEMENTS

The authors would like to acknowledge and thank information specialist Anne-Marie Klint Jørgensen and Bjørn Christian Viinholt Nielsen for running the database searches, Rikke Eline Wendt for being involved in the review process, the research assistants doing the screening, and senior researcher Trine Filges and researcher Jens Dietrichson for statistical advice.

CONTRIBUTERS

Signe Boe Rayce co-led the review process, contributed to study design, screening, data extraction, data synthesis, performed risk of bias judgement and meta-analysis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Ida Scheel Rasmussen contributed to study design, contributed to screening, data extraction, data synthesis, performed risk of bias, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Sihu Klest and Joshua Patras contributed to study design, data synthesis, critically revised the manuscript, and approved the final manuscript as submitted.

Maiken Pontoppidan conceptualized and designed the study, co-led the review process, contributed to screening, data extraction, and data synthesis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

COMPETING INTERESTS: The authors state that they have no conflicting interests.

FUNDING: Signe Boe Rayce and Ida Scheel Rasmussen were supported by a grant from the Danish Ministry of Social Affairs and the Interior. Maiken Pontoppidan was supported by the Danish Ministry of Social Affairs and the Interior and grant number 7-12-0195 from TrygFonden.

FINANCIAL DISCLOSURE: The authors have no financial relationships relevant to this article to disclose.

DATA SHARING STATEMENT: No additional data are available

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Online table 1 Risk of Bias of included studies for child development and parent-child relationship outcomes

Online figure 1 Meta-analysis of studies reporting internalizing behavior at post-intervention

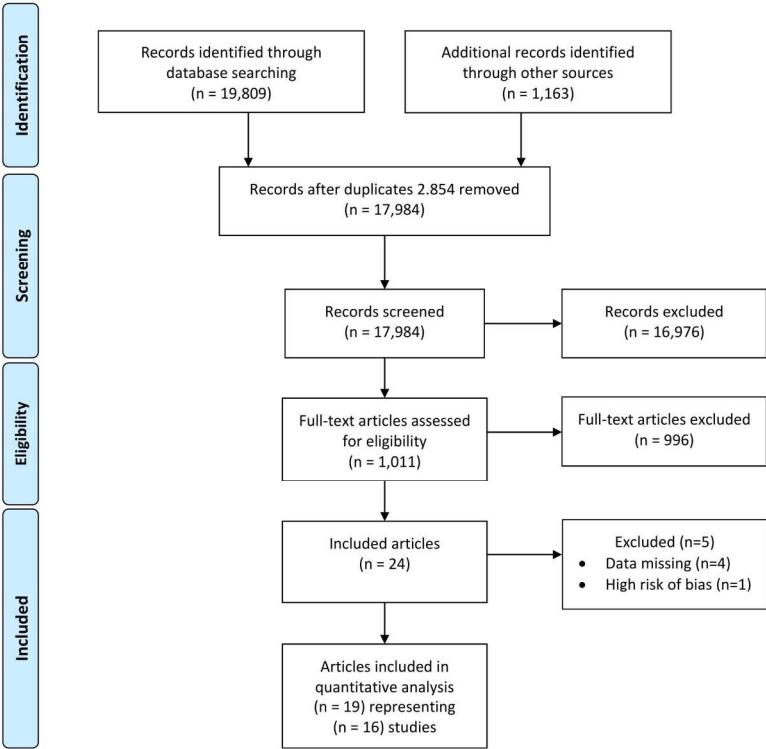
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Figure 1 Flow diagram for study selection process



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Figure 1 Flow diagram for study selection process

215x279mm (220 x 220 DPI)

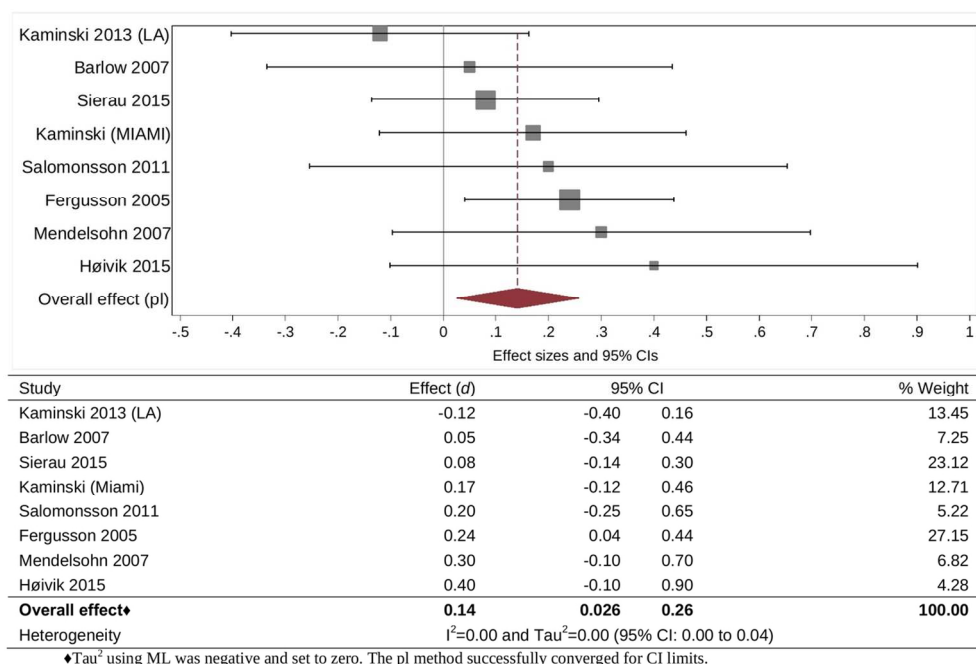


Figure 2 Meta-analysis of studies reporting child behavior outcomes at post-intervention

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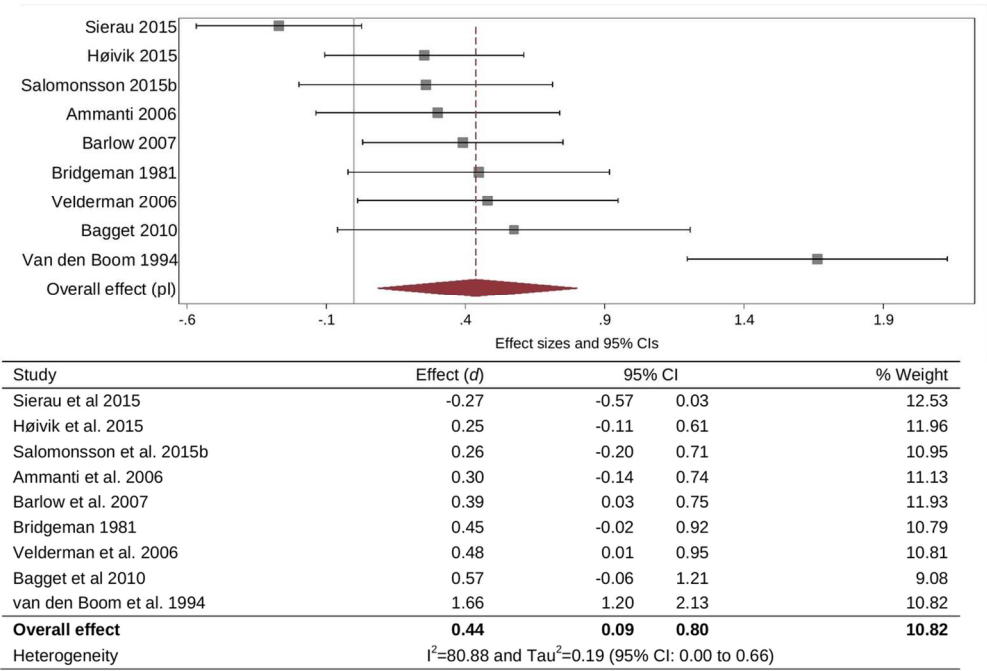


Figure 3 Meta-analysis of studies reporting parent-child relationship outcomes at post-intervention

116x80mm (300 x 300 DPI)

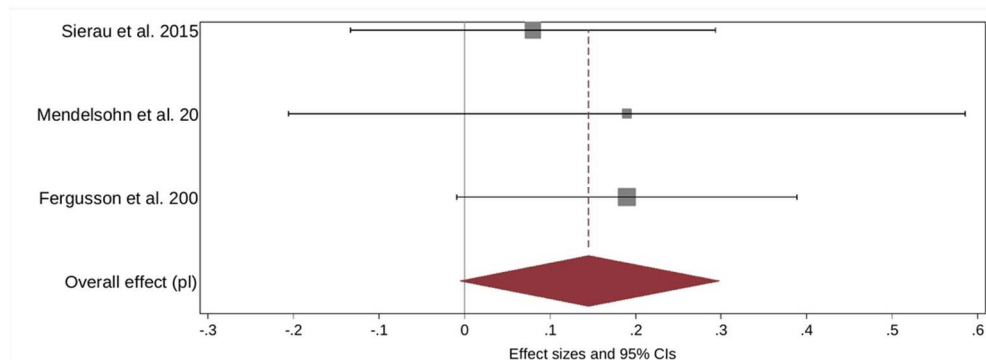
Online Table 1 Risk of Bias of included studies for child development and parent-child relationship outcomes

		Sequence generation	Allocation concealment	Blinding of outcome assessor	Incomplete outcome data	Free of selective reporting	A priori protocol	Free of other bias
	Outcome measures /Risk of bias domains							
Child development								
Barlow et al. 2006		L	L	-	-	-	U	-
	BITSEA/ Competence/Problems (Child behavior)	-	-	3	1	U	-	3
	BSID-II (Child cognitive and psychomotor development) BRS (Child behavior)	-	-	2	1	U	-	3
Bridgeman 1981		U	U	-	-	-	U	-
	Stanford-Binet (Child cognitive development) CFI (Child cognitive development) Pacific (Child cognitive development) Ammons (Child Communication/language development)	-	-	1	4	U	-	U
Kaminski et al. 2013*	DECA (Child behavior) SDQ (Child behavior)	L	L	3	3	1	Yes	1
Katz et al. 2011	BSID-II (Child cognitive and psychomotor development) BRS Bayley-II (Child behavior)	L	U	U	4	U	U	3
Mendelsohn et al. 2007		L	L	-	-	-	U	-
	BSID-II/MDI (Child cognitive development) PLS-3 (Child Communication/language development)	-	-	1	3	U	-	1
	CBCL/Internalizing/Externalizing/total (Child behavior)	-	-	3	3	U	-	1
Taylor et al. 1997	BSID II (Child cognitive and psychomotor development) CBCL (Child behavior)	L	U	1	3	U	U	1
		-	-	3	2	1	-	1
Fergusson et al. 2005	ITSEA/Externalizing/Internalizing/Total (Child behavior)	L	U	3	2	U	U	2
Fergusson et al. 2013		L	U	-	-	-	U	-
	SDQ (Child behavior - parent-rated)	-	-	3	2	U	-	2
	SDQ (Child behavior – teacher-rated)	-	-	2	2	U	-	2
Høivik et al. 2015	ASQ:SE (Child behavior)	H	H	3	4	1	Yes	U
Salomonsson et al 2011	ASQ:SE (Child behavior)	L	L	3	1	U	U	U
Salomonsson et al 2015a		L	L	-	-	-	U	-
	ASQ:SE (Child behavior) SDQ (Child behavior – parent-reported)	-	-	3	1	U	-	U
	SDQ (Child behavior – teacher-reported)	-	-	2	1	U	-	U
	CGAS (Child behavior)	-	-	1	1	U	-	U
Sierau et al. 2015		L	U	-	-	-	U	-
	BSID II/MDI/PDI (Child cognitive and psychomotor development) BRS Bayley-II (Child behavior) SETK-2 (Child Communication/language)	-	-	1	3	U	-	1
	ELFRA 1 and 2 (Child Communication/language) CBCL/Internalizing/Externalizing (Child behavior)	-	-	3	3	U	-	1

		Sequence generation	Allocation concealment	Blinding of outcome assessor	Incomplete outcome data addressed	Free of selective reporting	A priori protocol	Free of other bias
	Outcome measures /Risk of bias domains							
Parent-child relationship								
Ammaniti et al. 2006	Scales of Mother-Infant Interactional Systems (Parent-child relationship)	U	U	1	U	U	U	1
Bagget et al. 2010	Landry (Parent-child relationship)	U	U	1	1	U	U	1
Barlow et al. 2006	CARE-Index/ Maternal sensitivity/Infant cooperativeness (Parent-child relationship, maternal sensitivity)	L	L	2	1	U	U	3
Bridgeman 1981*	Mother-child relationship (based on Ainsworth) (Parent-child relationship)	U	U	1	4	U	U	U
Cassidy et al. 2013	SSP (Mother-Infant attachment)	U	U	1	1	U	Yes	1
Velderman et al 2006*	Maternal sensitivity (Ainsworth) (Maternal sensitivity) SSP (Mother-Infant attachment)	U	U	1	1	U	U	3
Taylor et al. 1997	NCATS (Parent-child relationship)	L	U	1	3	U	U	1
van den Boom 1994*	Maternal interactive behavior (Parent-child relationship) Infant interactive behavior (Parent-child relationship) SSP (Mother-Infant attachment)	U	U	1	U	U	U	1
van den Boom 1995*	SSP (Mother-Infant attachment) Mother-child interaction (based on Ainsworth)(Parent-child relationship, maternal sensitivity)	U	U	1	2	1	U	1
Høivik et al. 2015	EAS (Parent-child relationship)	H	H	1	2	1	Yes	U
Salomonsson et al 2015b		L	L	-	-	-	U	-
	SSAP (Mother-Infant attachment)	-	-	1	1	U	-	U
	EAS (Parent-child relationship)	-	-	1	U	U	-	2
Sierau et al. 2015	MBRS revised/Affectivity/Responsiveness (Parent-child relationship)	L	U	1	3	U	U	1

*Note: Risk of bias was conducted for each outcome. When risk of bias was the same for all included outcomes, only one score is provided in the table.
Note: In the 5-point scale 1 corresponds to low risk of bias and 5 correspond to high risk of bias. L= low risk of bias; H=high risk of bias; U= unclear risk of bias

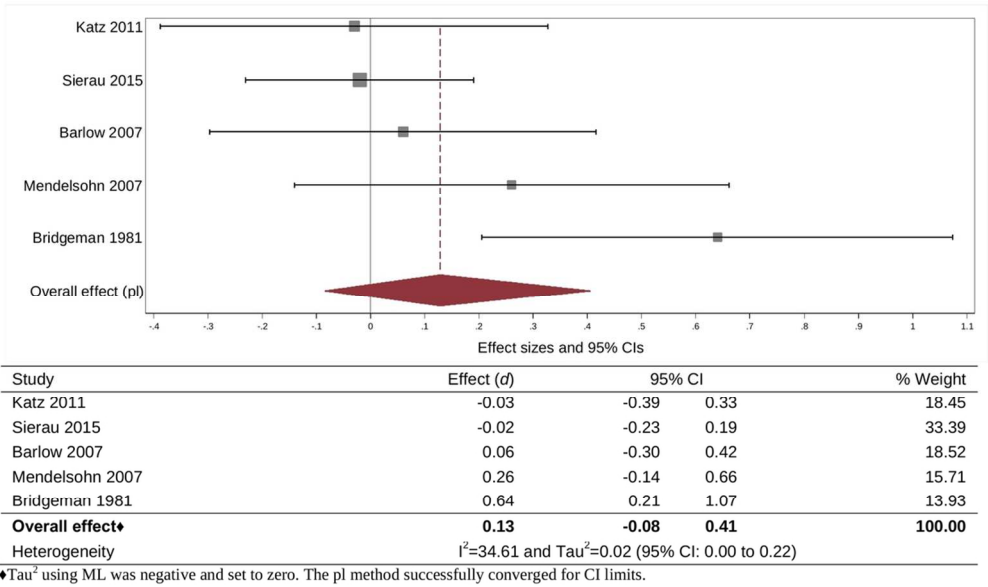
Ammons: Ammons full range picture vocabulary test, ASQ:SE: Ages and Stages Questionnaires: Social Emotional, BITSEA: Brief Infant Toddler social and emotional assessment, BRS Bayley-II: Behavior Rating Scale, BSID-II: Bayley Scales of Infant Development, CBCL: Child Behavior Checklist, CFI: Concept Familiarity Index, CGAS: Children's Global Assessment Scale, DECA: The Devereux Early Childhood Assessment, EAS: Emotional availability scales, ELFRA 1 and 2: Elternfragebögen für die Früherkennung von Risikokindern, ITSEA: Infant Toddler social and emotional assessment, Landry: The Landry Parent-Child Interaction Scales, MBRS revised: Maternal behavior rating scale, NCATS: The nursing child assessment teaching scale, Pacific: Meyers Pacific Test Series, PLS-3: Preschool language scale-3, SDQ: Strenths and Difficulties Questionnaire, SETK-2: Sprachentwicklungstest für zweijährige Kinder, SSAP: Story Stem Assessment Profile, SSP: Strange situation procedure, Stanford-Binet: Stanford-Binet Intelligence Scales



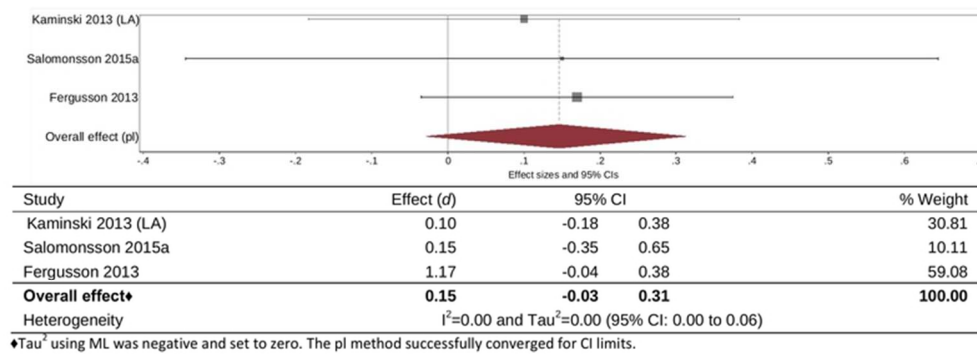
Study	Effect (d)	95% CI		% Weight
Sierau 2015	0.08	-0.13	0.29	40.85
Mendelsohn 2007	0.19	-0.21	0.59	11.95
Fergusson 2005	0.19	-0.01	0.39	47.20
Overall effect	0.15	-0.01	0.30	100.00
Heterogeneity	$I^2=0.00$ and $\text{Tau}^2=0.00$ (95% CI: 0.00 to 0.05)			

♦Tau² using ML was negative and set to zero. The pl method successfully converged for CI limits.

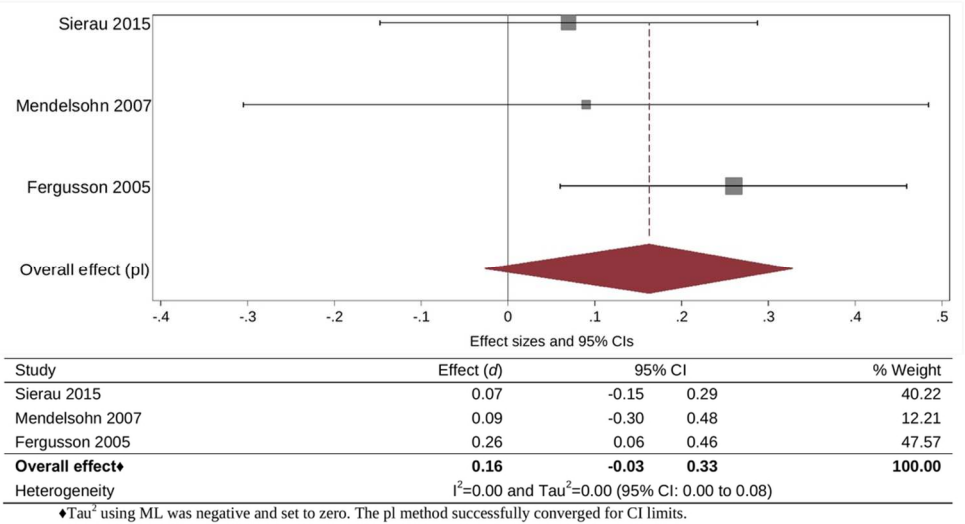
96x54mm (300 x 300 DPI)



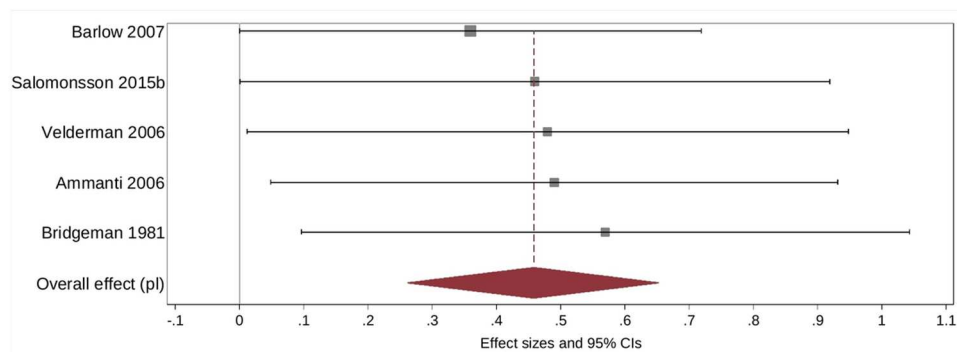
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67x26mm (300 x 300 DPI)



99x55mm (300 x 300 DPI)



Study	Effect (d)	95% CI		% Weight
Barlow et al. 2007	0.36	0.00	0.72	29.06
Salomonsson et al. 2015b	0.46	0.00	0.92	17.82
Velderman et al. 2006	0.48	0.01	0.95	17.13
Ammanti et al. 2006	0.49	0.05	0.93	19.26
Bridgeman 1981	0.57	0.10	1.04	16.75
Overall effect♦	0.46	0.26	0.65	100.00
Heterogeneity	I ² =0.00 and Tau ² =0.00 (95% CI: 0.00 to 0.06)			

♦Tau² using ML was negative and set to zero. The pl method successfully converged for CI limits.

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PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5-6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7 table 1
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6-7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary file
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7 figure 1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7-8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8-9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	8-10



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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8-9
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 1 Flow diagram
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 2+3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Online table 1
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Tables 4+5
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	20-26, Figure 2-3, Online figure 1-5
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	16-17
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	26-27
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	27-30
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	27-30
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	30-31
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	32



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From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org. Page 2 of 2

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BMJ Open

The effects of parenting interventions for at-risk parents with infants: A systematic review and meta-analyses

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015707.R1
Article Type:	Research
Date Submitted by the Author:	10-Mar-2017
Complete List of Authors:	Rayce, Signe; Nationale Forskningscenter for Velfard, Child and Family Rasmussen, Ida ; Nationale Forskningscenter for Velfard, Child and Family Klest, Siu; University of Tromsø, The Regional Centre for Child and Youth Mental Health and Child Welfare - North Patras, Joshua; University of Tromsø, The Regional Centre for Child and Youth Mental Health and Child Welfare - North Pontoppidan, Maiken; Nationale Forskningscenter for Velfard, Child and Family
Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	General practice / Family practice, Paediatrics, Public health
Keywords:	PAEDIATRICS, Community child health < PAEDIATRICS, PRIMARY CARE, Child & adolescent psychiatry < PSYCHIATRY, PUBLIC HEALTH, Clinical trials < THERAPEUTICS

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The effects of parenting interventions for at-risk parents with infants: A systematic review and meta-analyses

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Word count: 4271

Keywords: Child development, infant development, parent-child relationship, parenting intervention, systematic review.

ABSTRACT

Objectives: Infancy is a critical stage of life, and a secure relationship with caring and responsive caregivers is crucial for healthy infant development. Early parenting interventions aim to support families in which infants are at risk of developmental harm. The objective was to systematically review the effects of parenting interventions on child development and on parent–child relationship outcomes for at-risk families with infants aged 0–12 months.

Design: A systematic review and meta-analyses. We extracted publications from 10 databases in June 2013, January 2015, and June 2016, and supplemented with grey literature and hand search. We assessed risk of bias, calculated effect sizes, and conducted meta-analyses.

Inclusion criteria: 1) Randomized controlled trials of structured psychosocial interventions offered to at-risk families with infants aged 0–12 months in Western OECD countries, 2) Interventions with a minimum of three sessions and at least half of these delivered postnatally, and 3) Outcomes reported for child development or parent–child relationship.

Results: Sixteen studies were included. Meta-analyses were conducted on seven outcomes represented in 13 studies. Parenting interventions significantly improved child behavior ($d=0.14$; 95% CI: 0.03 to 0.26), parent–child relationship ($d=0.44$; 95% CI: 0.09 to 0.80), and maternal sensitivity ($d=0.46$; 95% CI: 0.26 to 0.65) post-intervention. There were no significant effects on cognitive development ($d=0.13$; 95% CI: -0.08 to 0.41), internalizing behavior ($d=0.16$; 95% CI: -0.03 to 0.33), or externalizing behavior ($d=0.16$; 95% CI: -0.01 to 0.30) post-intervention. At long-term follow-up we found no significant effect on child behavior ($d=0.15$; 95% CI: -0.03 to 0.31).

Conclusions: Interventions offered to at-risk families in the first year of the child's life appear to improve child behavior, parent–child relationship, and maternal sensitivity post-intervention, but not child cognitive development, internalizing, or externalizing behavior. Future studies should incorporate follow-up assessments to examine long-term effects of early interventions.

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Strengths and limitations of this study:

- Comprehensive search strategy and screening procedure
- Evaluation of child development and parent–child relationship outcomes
- Meta-analyses conducted on seven outcomes
- Few studies provide follow-up data
- Limited information on implementation

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INTRODUCTION

The first year of a child's life is characterized by rapid development that forms the foundation for lifelong developmental trajectories. A healthy environment is crucial for infants' emotional well-being and future physical and mental health.[1,2]

Experiencing severe adversity early in life can alter a child's development and lead to toxic stress responses, impairing brain chemistry and neuronal architecture.[3] For infants, severe adversity typically takes the form of caregiver neglect and physical or emotional abuse. The highest rates of child neglect and violent abuse occur for children younger than five,[4,5] with the most severe cases, which involve injury or death, occurring predominantly to children under the age of one.[6]

Mental health problems are common in infants, but symptoms are often less intrusive and less distinctly identifiable than for older children.[7–12] The Copenhagen Child Cohort study (CCC2000) found a prevalence rate of 18% for axis I diagnoses (according to DC: 0–3) in children aged 18 months, with regulatory disorders and disturbances in parent child–relationships being the most frequent mental health diagnoses.[8] The high prevalence in mental health diagnoses is important to note, as early onset of behavioral or emotional problems and adverse environmental factors increases the risk for negative outcomes later in life, such as substance abuse, delinquency, violence, teen pregnancy, school dropout, continued mental health problems, and long-term unemployment.[1,2,8,13–18]

Becoming a parent can be stressful and challenging,[19–21] particularly for parents who have experienced trauma, abuse, poverty, or other stressors.[22] Early-intervention parenting programs aim to assist parents with the challenges they experience. Most of these interventions teach caregivers specific strategies and skills

that foster healthy child development with an emphasis on promoting warm and responsive caregiving.[23]

Existing systematic reviews of the effects of parenting interventions offered to families with young children have shown mixed results.[14,24–29] In a review of 78 studies aimed at families with children aged 0–5 years, Piquero et al. found an average effect size (*g*) of 0.37 for decreased antisocial behavior and delinquency for intervention children.[14] Based on 22 studies, Barlow et al. concluded that there is tentative support for the effect of group-based interventions on emotional and behavioral adjustment in children aged 0–3 years.[28] Macbeth et al. found medium effect sizes for child or parent outcomes in a review of the Mellow Parenting intervention for families with children aged 0–8 years.[24] Barlow et al. found some evidence suggesting that parenting programs for teenage parents may improve parent–child interaction.[26] Barlow et al. reviewed parent–infant psychotherapy for high-risk families with infants aged 0–24 months; they found that infant attachment improved, but they found no effects on other outcomes.[27] Reviewing interventions offered to a universal group of parents of infants aged 0–1 year, Pontoppidan et al. found mixed and inconclusive results for child development and parent–child relationship outcomes.[25] Peacock et al. examined the effects of home visits for disadvantaged families with children aged 0–6 years and found improved child development outcomes when the intervention was implemented early.[30]

The existing reviews include very few studies of interventions for at-risk parents that are initiated within the first year of the infants’ life. Therefore, we do not know if early preventive parenting interventions are effective in improving child development or parent–child relationship outcomes. The aim of this review was to

systematically review the effects of parenting interventions offered to at-risk families with infants aged 0–12 months. We included randomized controlled trials of parenting interventions reporting child development or parent–child relationship outcomes at post-intervention or follow-up.

METHODS

Search strategy

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We did not register a protocol. The database searches were performed in June 2013 and were updated in January 2015 and June 2016. We searched ten international bibliographic databases: Campbell Library, Cochrane Library, CRD (Centre for Reviews and Dissemination), ERIC, PsycINFO, PubMed, Science Citation Index Expanded, Social Care Online, Social Science Citation Index, and SocIndex. Operational definitions were determined for each database separately. The main search was made up of combinations of the following terms: infant*, neonat*, parent*, mother*, father*, child*, relation*, attach*, behavi*, psychotherap*, therap*, intervention*, train*, interaction, parenting, learning, and education. The searches included Medical Subject Headings (MeSH), Boolean operators, and filters. Publication year was not a restriction. Furthermore, we searched for grey literature, hand searched four journals, and snowballed for relevant references.

Eligibility criteria and study selection

We screened all publications based on title and abstract. Publications that could not be excluded were screened based on the full-text version. Table 1 shows the inclusion and exclusion criteria.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Population	
At-risk population of parents of infants 0-12 months old in western OECD countries	Studies including specific groups such as young mothers (mean age <20 years), divorced parents, parents with mental health problems such as schizophrenia and abuse and children born pre-term, at low birth weight or with congenital diseases.
Intervention	
Structured psychosocial parenting intervention consisting of at least three sessions and initiated either antenatal or during the child's first year of life with at least half of the sessions delivered postnatally.	Interventions not focusing specifically on parenting (e.g. baby massage, reading sessions with child, or breastfeeding interventions), and unstructured interventions (e.g. home visits not offered in a structured format).
Control group	
No restrictions were imposed. All services or comparison interventions received or provided to the control group were allowed.	
Outcome	
Child development and/or parent-child relationship outcomes	Studies reporting only physical development or health outcomes such as height, weight, duration of breastfeeding, and hospitalization. Papers with insufficient quantitative outcome data to generate standardized mean differences (Cohen's d), odds ratios (OR) and confidence intervals (CI).
Design	
Randomized controlled trials (RCT) or quasi-RCTs.	Other study designs such as case control, cohort, cross sectional, and systematic reviews
Publication type	
Studies presented in peer-reviewed journals, dissertations, books or scientific reports.	Abstracts or conference papers. Studies published in languages others than English, German or the Scandinavian languages (Danish, Swedish and Norwegian).

We excluded studies that examined parenting interventions aimed at specific risk-groups such as teen mothers; parents with severe mental health problems; or parents with children born pre-term, at low birth weight, or with congenital diseases. Families experiencing difficulties such as these have specific needs, and interventions aimed at these groups may be more targeted when compared to parenting interventions aimed at broader, at-risk groups of parents. Since our focus

was parenting interventions aimed at at-risk parents in general, we excluded studies developed for specific risk-groups.

Each publication was screened by two research assistants under close supervision by MP and SBR. Uncertainties regarding inclusion were discussed with MP and SBR. Screening was performed in Eppi-Reviewer 4.

Data extraction and risk of bias assessment

We developed a data extraction tool for the descriptive coding and extracted information on 1) study design, 2) sample characteristics, 3) setting, 4) intervention details, 5) outcome measures, and 6) child age at post-intervention and at follow-up. Information was extracted by one research assistant and subsequently checked by another reviewer. Disagreements were discussed with MP or SBR. Primary outcomes were child behavior and the parent–child relationship. Secondary outcomes were other child development markers such as cognitive development, language/communication, psychomotor development, parent sensitivity, and attachment classification. When reported, both total scores and subscale scores were extracted.

Numeric coding of outcome data was conducted by ISR and checked by MP or SBR. We resolved disagreements by consulting a third reviewer. Risk of bias was assessed separately for each relevant outcome for all studies based on a risk-of-bias model developed by Professor Barnaby Reeves and the Cochrane Nonrandomized Studies

Method Group (Reeves, Deeks, Higgins, & Wells, unpublished data, 2011). This extended model is organized and follows the same steps as the existing risk-of-bias model presented in the Cochrane Handbook, chapter 8.[31] The assessment was conducted by ISR and SBR. Any doubts were discussed with a third reviewer.

Analyses

We calculated effect sizes for all relevant outcomes for which sufficient data was provided. Effect sizes were reported using standardized mean differences (Cohen’s *d*) with 95% confidence intervals for continuous outcomes. Data included post-intervention and follow-up means, raw standard deviations, and sample size. Alternatively, *t*-values, *F*-tests, χ^2 , *p*-values, mean differences, eta-square and β -coefficients were used. For dichotomous outcomes, we used odds ratios (ORs) with 95% confidence intervals as the effect size metric when presenting the effects of the individual studies. When used in meta-analyses, ORs were converted to *d* using the method presented in Chin (2000).[32] The data used to calculate ORs were number of events and sample sizes. We contacted the corresponding author for more information if a paper presented insufficient information regarding numeric outcomes. When available, we used data from adjusted analyses to calculate effect sizes. When using the adjusted mean difference, we used the unadjusted standard deviations in order to be able to compare the effect sizes calculated from unadjusted and adjusted means, respectively. To calculate effect sizes, we used the Practical Meta-Analysis Effect Size Calculator developed by David B. Wilson at George Mason University and provided by the Campbell Collaboration.

Meta-analysis was performed when the intervention outcome and the time of assessment were comparable. If a single study provided more than one relevant measure or only subscales for a given meta-analysis, then the effect sizes of the respective measures were pooled into a combined measure.

Random effects inverse variance weighted mean effect sizes were applied and 95% confidence intervals were reported. Studies with larger sample sizes were therefore given more weight, all else being equal. Due to the relatively small number of studies and an assumption of between-study heterogeneity, we chose a random-effects model using the profile-likelihood estimator as suggested in Cornell 2014.[33] Variation in standardized mean difference that was attributable to heterogeneity was assessed with the I^2 . The estimated variance of the true effect sizes was assessed by the Tau^2 statistic. When indication of high heterogeneity ($I^2 > 75\%$) was found, sensitivity analyses were conducted, removing one study at a time in order to identify a potential source of heterogeneity. The small number of studies in the respective meta-analyses did not allow for subgroup analyses. Results were summarized for child development (behavior, cognitive development, psychomotor development, and communication/language) and parent-child relationship (relationship, sensitivity, and attachment classification) outcomes for the following assessment times: post-intervention (PI), short-term (ST), mid-term (MT), and long-term (LT) follow-up.

RESULTS

Description of studies

The literature search identified 17,984 articles after the removal of duplicates. A flow diagram for the process of study inclusion is illustrated in figure 1. Nineteen papers representing 16 individual studies were included. Kaminski et al. 2013 represented two trials (LA & Miami) and is handled as two studies when reporting results.[34] Four studies were excluded, as they provided insufficient numeric data to calculate effects sizes and Cis.[35–38] One study was excluded due to unacceptably high risk of bias.[39]

Figure 1 about here

Included studies

Except for one study,[40] which compared a group-based intervention to an individual-based intervention, all studies compared interventions to a no-intervention control or to treatment as usual (TAU) . A few studies offered minor interventions such as psychoeducation and social worker contact to the control group.[41–44] Eight studies were American,[34,40–42,44–46]two were conducted in the Netherlands,[47–49] and one study each was from Sweden,[50–52] Germany,[53] Italy,[54] New Zealand,[55,56] Norway,[43] and the United Kingdom.[57] The oldest study was published in 1981[45] and the most recent studies were published in 2015.[43,52,51,53] Sample size ranged from 40 participants [41] to 755.[53]

Participant characteristics

Table 2 shows study participant characteristics. All families exhibited at least one risk factor such as poverty, low education, or living in deprived areas. Some samples were further characterized by, for example, insecure attachment, risk of developmental delay, or having a difficult or irritable infant. We did not include studies targeting families with more severe problems such as drug abuse, incarceration, or chronic diseases.

Mothers' mean age ranged from 21–33 years. Four studies recruited primiparous mothers,[42,48,47,49,53] five studies also included mothers with more than one child, [41,43,44,46,52,51,50] and seven studies did not report parity.[34,40,45,54,56,55,57]

Table 2 Participant characteristics

Study	Country	Risk	Mother mean age at start in years	Child age at start in months	Primiparous %	Intervention, n	Control, n
Ammaniti et al[54]	Italy	Depressive or psychosocial risk	33	Third trimester	Not reported	47	44
Baggett et al[41]	USA	Low income	Intervention: 25; Control: 27	~4	Mean number of children: 1.75	20	20
Barlow et al[57]	UK	Vulnerable	< 17 years: Intervention:17.9%; Control:22.2 %	Second trimester	Not reported	68	63
Bridgeman et al[45]	USA	Low income	17 – 35	3-5	Not reported		Unclear ‡
Cassidy et al[42]	USA	NBAS or low income	24	6.5-9	100	85	84
Fergusson et al[55] & Fergusson et al[56]	New Zealand	Two or more risk factors present	Mother: Intervention: 24; Control: 24 Father: Intervention: 27; Control: 27	Not reported (Recruited within 3 months of birth)	Not reported	206	221
Hoivik et al[43]	Norway	Interactional problems	30	7.3	72	88	70
Kaminski et al[34]	USA	Low income	24	Prenatally (LA), at birth (Miami)	Not reported	338	236
Katz et al[44]	USA	African American with inadequate prenatal care	25	0	Mean number of children: 2.9	146	140
Mendelsohn et al[46]	USA	Low educated latina mothers	Intervention: 30; Control: 30	0.5	Intervention: 21.2; control: 36.2	77	73
Salomonsson et al[50]Salomonsson et al[51] & Salomonsson et al[52]	Sweden	Worried mothers	Intervention: ~34; Control: ~32	Intervention:4.4; Control:5.9	Intervention:81; Control:78	40	40
Sierau et al[53]	Germany	Economic- and social risk factors	Intervention: 21; Control: 22	Third trimester	100	394	361
Taylor et al[40]	USA	Poverty, single marital status, low education, age <20, previous substance abuse, or a history of abuse	Intervention (n): <20: 44, 20-30:122, >30:34; Control: <20:58, 20-30:108, >30:34	3	Not reported	50	50
van den Boom et al[47] & van den Boom et al[48]	Netherlands	Lower-class mothers with irritable infants	Mother: 25 Father: Intervention:28; control:29	6	100	50	50
Velderman et al [49]	Netherlands	Insecure attachment	28	~7	100	54	27

‡ The study only reported number of participants in each analysis

Interventions

Table 3 presents the intervention details. Eight studies offered individual home visits,[42–44,48,47,49,53,54,56,55,57] three studies offered individual sessions (outside the home),[45,46,52,51,50] one study offered group sessions,[40] one study offered web-coaching,[41] two studies combined individual sessions and group sessions,[34] and one study combined home visits and group sessions.[44]

Intervention was initiated prenatally in four studies,[34,53,54,57] and 12 studies initiated intervention after the child was born.[34,40–46,48,47,49,52,51,50,56,55]

The duration of the interventions varied from relatively short interventions (≤ 6 months) [41,42,48,47,49,52,51,50] to medium-length interventions (7–12 months) [40,43,44,54,57] to long interventions (≥ 24 months).[34,45,46,53,56,55]

Table 3 Intervention characteristics

Study	Name of intervention	N	Intervention				Control	Outcome	
			Begins	Intensity	Format	Ends/duration		Measure	Child age
Ammaniti et al.[54]	Home Visiting Program (HV)	91	8 months pregnant	Weekly and every second week. ~ 36 sessions	Home visits	Ends: 12 months of age	No intervention	Parent-child relationship	12 months
Baggett et al.[41]	Infant Net	40	3-8 months of age	10 online sessions + 1 read to me session + weekly coach calls	Web-coaching	Duration: 6 months	TAU+provided computer and internet technology	Parent-child relationship	~10 months
Barlow et al.[57]	Intervention based on The Family Partnership Model	131	6 months antenatal	Weekly (mean sessions 41.2)	Home visits	Duration: 18 months	TAU	Parent-child relationship Child development	12 months
Bridgeman et al.[45]	Parent Child Development Center (PCDC)	Uncl ear†	2 months of age	Twice a week for a total of six hours	Individual sessions	Ends: 36 months of age	No intervention	Parent-child relationship Child developmentΔ	36 months
Cassidy et al.[42]	Circle of security, home visiting	174	6.5-9 months of age	1 hour every 3 weeks	Home visits	Duration: 3 months	Psychoeducational sessions (3*1 hour)	Parent-child relationshipΔ	12 months
Fergusson et al.[55] & Fergusson et al.[56]	Early Start (2 levels of intensity)	443	Recruited within 3 months of birth	Varied. Low level: up to 2.5 hours per 3 months	Home visits	Duration 36 months	No intervention	Child development	~36 months ~9 years
Høivik et al.[43]	Video feedback, Marte Meo	158	Varies, between 0-24 months of age ~7.3 months of age	8 sessions, 9-13 months (mean 11.5 months)	Home visits	Duration: 9-13 months	TAU + health center nurses if needed	Parent-child relationship Child development	~9-10 months ~15-16 months
Kaminski et al., Los Angeles[34]	Legacy for Children	574	Prenatal in LA	Weekly (2.5 hour) for 3 years in LA	Group sessions and individual sessions	Duration: 3 years in LA	No intervention	Child development	~36 months ~48 months ~60 months
Kaminski et al., Miami [34]	Legacy for Children		At birth in Miami	Weekly (1.5 hour) for 5 years in Miami	Group sessions and individual sessions	Ends: 5 years of age in Miami	No intervention	Child development	~60 months
Katz et al.[44]	Pride in Parenting	286	At birth	Weekly from birth through 4 month and biweekly from 5 to 12	Home visits+groups	Ends: 12 months of age	TAU+monthly contacts from	Child development	12 months

Study	Name of intervention	N	Intervention				Control	Outcome	
			Begins	Intensity	Format	Ends/duration		Measure	Child age
	Program (PIP)			months	sessions		a hospital-based social worker		
Mendelsohn et al.[46]	Video Interaction Project (VIP)	150	2 weeks postpartum	12 sessions (30-45 min. each)	Individual sessions	Ends: 36 months of age	TAU	Child development	33 months
Salomonsson et al.[50], Salomonsson et al[51] & Salomonsson et al[52]	Psychoanalytic treatment	80	Varied: Infants below 1½ years, mean age <6 months	23 session (median), 2-3 hour pr. week	Individual sessions	Duration: Unclear, assumingly 6 months	TAU	Parent-child relationship Child development	4½ years ~11 months ~54 months
Sierau et al[53]	Pro Kind	755	36 gestational weeks (assumingly)	Weekly (first 4 weeks after program intake and 4 weeks after birth), bi-weekly, and monthly (last half year of treatment)	Home visits	Ends: 24 months old (assumingly)	TAU	Parent-child relationship Child development	24 months
Taylor et al[40]	Group well child care (GWCC)	220	3 months of age	7 sessions (45-60 min.) up to 15 months	Group sessions	Ends: ~15 months of age	Individual well child care (IWCC)†	Parent-child relationshipΔ Child developmentΔ	~ 15 months
van den Boom et al[47] & van den Boom et al[48]	-	100	6 months of age (baseline 10 days after birth)	1 sessions (2 hours) every 3 weeks for 3 months	Home visits	Ends: 9 months of child's age	No intervention	Parent-child relationship	9 months 12 months 18 months
Velderman et al[49]	1. VIPP 2. VIPP-R	81	~ 7 months of age	4 visits (1.5-3 hours) over 9-12 weeks	Home visits	Duration: 9 to 12 weeks	No intervention	Parent-child relationship	11-13 months 13 months

◇ Not a standardized test

† Two active intervention groups, **no** control group

Δ Outcome(s) not included in meta-analysis

‡ Study only reported number of participants in each analysis

Outcomes

Child development and the parent–child relationship were measured based on parent-report questionnaires, teacher-report questionnaires, structured interviews, and videos. Five studies reported only child development outcomes,[34,44,46,56,55] five reported only parent–child relationship outcomes,[41,42,48,47,49,54] and six reported both.[40,43,45,52,51,50,53,57] Timing of assessment was divided into four assessment times: (1) post-intervention follow-up (immediately after intervention ending), (2) short-term follow-up (less than 6 months after intervention ending), (3) medium-term follow-up (7–12 months after intervention ending), and (4) long-term follow-up (more than 12 months after intervention ending). All studies reported a post-intervention outcome. Two studies reported an outcome at short-term follow-up,[43,48,47] two at medium-term follow-up,[34,47] and three at long-term follow-up.[34,52,51,50,56,55]

Risk of Bias

The risk of bias assessments are shown in the online table 1 and are divided into child development outcomes and parent-child relationship outcomes. Many studies provided insufficient information for at least two domains, thereby hindering a clear judgment for risk of bias. Risk of bias generally ranged between low and medium. However, three studies had outcomes where one or two domains had a moderate risk of bias.[43–45] Two studies had outcomes with high risk of bias in one domain.[43,45] Based on an overall judgement across risk-of-bias domains, two outcomes (CTBS math and BTBS reading scores) [45] and one study [39] were excluded from the review. The reasons were, on the one hand, high risk of bias in relation to “incomplete data addressed” combined with unclear risk of bias

1 judgements in all other domains,[45] and, on the other hand, the pronounced baseline
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3 imbalance not being addressed.[39]
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6 The outcomes included in the child development meta-analyses were characterized
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8 by low to medium and unclear risk of bias domains, whereas the meta-analyses on
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10 parent–child relationship outcomes primarily included outcomes with a relatively
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12 low or unclear risk of bias. Two studies represented in the meta-analyses of both
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14 child development and parent–child relationship outcomes had domains assessed as
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16 having moderate or high risk of bias.[43,45]
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19 20 21 **Child development outcomes at post-intervention**

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23 Table 4 presents the study outcomes for the individual studies.
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Table 4 Child development outcomes as reported across studies included in the systematic review

Study	Measure	Assess ment	Child age in month s	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
PI	Behavior										
Barlow et al. 2007[57]	Total problem score BITSEA ◯	Q	12	55	33.52	38.81	49	35.55	39.63	0.05(-0.33;0.44)	
	Competence BITSEA	Q	12	53	14.06	3.65	43	13.37	3.53	0.19(-0.21;0.60)	
	BRS	O	12	62	38.37	5.71	59	38.69	5.5	-0.06(-0.41;0.30)	
Høivik et al. 2015[43]	Total score ASQ:SE	Q	~9-10	37			27			0.40(-0.10;0.90)	β=-7.22, SD of DV=18.51 ■
Salomonsson et al. 2011[50]	Total score ASQ:SE ◯	Q	~11	38	1.00	0.72	37	1.14	0.70	0.20(-0.26;0.65)	Becker's δ=0.25(adjusted for baseline ASQ:SE)
Sierau et al. 2015[53]	Internalizing CBCL ◯	Q	24	167	9.51	5.95	159	9.94	5.65	0.07(-0.14;0.29)	
	Externalizing CBCL ◯	Q	24	172	15.93	7.56	164	15.34	7.23	0.08(-0.13;0.29)	
	BRS	O	24	160	53.10	26.74	142	57.13	27.79	-0.15(-0.37;0.08)	
Fergusson et al. 2005[55]	Externalizing ITSEA (short)	Q	~36	207			184			0.19 (-0.01;0.39)	Cohen's d provided in paper
	Internalizing ITSEA (short)	Q	~36	207			184			0.26(0.06;0.47)	Cohen's d provided in paper
	Total problem score ITSEA(50 item)	Q	~36	207			184			0.24(0.04;0.44)	Cohen's d provided in paper
Kaminski et al. 2013, LA[34]	DECA Behavioral concerns	Q	36	126			78			-0.12(-.48;0.25) ✕	OR=0.81 (0.42;1.56)
	DECA Socioemotional problems	Q	36	127			79			-0.04(-0.49;0.43) ✕	OR=0.93(0.41;2.17)
Kaminski et al. 2013, Miami[34]	DECA Behavioral concerns	Q	60	121			73			0.32(-0.07;0.7) ✕	OR=1.78(0.88;3.57)
	DECA Socioemotional problems	Q	60	122			73			0.00(-0.48;0.49) ✕	OR=1.00(0.42;2.44)
	SDQ Conduct problems	Q	60	122			73			0.18(-0.14;0.52) ✕	OR=1.39(0.77; 2.56)
	SDQ Hyperactivity _i	Q	60	121			73			0.31(-0.21;0.84) ✕	OR=1.75(0.69;4.55)
	SDQ Peer problems	Q	60	121			73			-0.14(-.52;0.24) ✕	OR=0.78(0.39;1.54)
Mendelsohn et al. 2007[46]	Total problem score CBCL◯	Q	33	52	50.2	10.0	47	53.2	9.7	0.30(-0.09; 0.70)	
	Externalizing CBCL◯	Q	33	52	50.0	9.8	47	51.8	9.4	0.19(-0.21;0.58)	
	Internalizing CBCL◯	Q	33	52	52.9	9.9	47	53.8	9.3	0.09(-0.30;0.49)	
Katz et al. 2011[44]	BRS	O	12	73			51			0.83(-0.43;2.09) ✕	Normal/non-optimal: Intervention:72/1, control: 48/3, OR=4.5 (0.45; 44.5)
PI	Cognitive development										
Barlow et al. 2007[57]	MDI	O	12	62	93.74	10.98	59	93.03	10.89	0.06(-0.29;0.42)	
Katz et al. 2011 [44]	MDI	O	12	73	101.0	12.4	51	101.4	17.3	-0.03(-0.39;0.33)	
Taylor et al. 1997[40]	MDI	O	~15	50	99.3	14.8	50	100.4	14.3	-0.08(-0.47;0.32)▲	
Sierau et al. 2015[53]	MDI	O	24	180	87.37	14.74	167	87.64	14.74	-0.02(-0.23;0.19)	
Bridgeman et al. 1981, New Orleans, Louisiana[45]	Intelligence Stanford-Binet	O	36	46	104.22	10.36	52	96.69	12.20	0.66(0.25;1.07)	R=0.49 (incl.all independent variables)
	Concept attainment CFI	O	36	38	33.39	4.69	43	28.02	7.01	0.89(0.43;1.35)	
	Perception Pacific test series	O	36	32	32.09	5.29	42	30.00	6.86	0.34(-0.13;0.80)	
Mendelsohn et al. 2007[46]	MDI	O	33	52	86.1	7.5	45	83.9	9.7	0.26(-0.14;0.66)	
PI	Psychomotor development										

Study	Measure	Assessment	Child age in months	Intervention		Control		Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD
Katz et al. 2011[44]	PDI	O	12	73	95.1	13.6	51	93.1	11.9
Taylor et al. 1997[40]	PDI	O	~15	50	103.6	11.5	50	100	12.4
Sierau et al. 2015[53]	PDI	O	24	180	92.86	15.08	167	92.81	14.10
PI	Communication/language								
Bridgeman et al. 1981, New Orleans, Louisiana[45]	Ammons	O	36	34	13.44	3.38	38	11.11	3.09
Mendelsohn et al. 2007[46]	PLS-3	O	33	52	80.7	10.2	45	81.1	10.6
Sierau et al. 2015[53]	ELFRA	O	24	169	102.64	64.69	161	107.84	66.63
	SETK-2	O	24	141	0.78	0.58	128	0.80	0.61
SF	Behavior								
Høivik et al. 2015[43]	ASQ:SE	Q	~15-16	26			27		
MF	Behavior								
Kaminski et al. 2013 LA[34]	DECA Behavioral concerns	Q	48	124			78		
	DECA Socioemotional problems	Q	48	124			78		
	SDQ Conduct problems	Q	48	124			78		
	SDQ Hyperactivity _I	Q	48	124			78		
	SDQ Peer problems	Q	48	124			78		
LF	Behavior								
Fergusson et al. 2013[56]	SDQ \circ	Q	~108	199	9.91	0.91	171	10.08	1.06
Kaminski et al. 2013 LA[34]	DECA Behavioral concerns	Q	60	116			71		
	DECA Socioemotional problems	Q	60	117			73		
	SDQ Conduct problems	Q	60	116			71		
	SDQ Hyperactivity _I	Q	60	116			71		
	SDQ Peer problems	Q	60	116			71		
Salomonsson et al 2015a[51]	ASQ:SE	Q	54	32	0.98	0.90	32	0.88	0.68
	SDQ	Q _{parent}	54	32	8.17	5.54	31	7.39	5.19
	SDQ	Q _{teacher}	54	24	5.71	4.32	27	6.59	5.31
	CGAS Functioning	Q	54	31	78.39	12.8	30	68.87	14.74

✕ Calculation based on dichotomous outcome

○ Reverse scoring – high score is negative

■ Adjusted for ASQ baseline score

▲ No control group. Two interventions were compared.

U, unadjusted; Q, questionnaire; O, observation; PI, post-intervention; SF, short-term follow-up (≤ 6 months post intervention); MF, mid-term follow-up (7-12 months); LF, long-term follow-up (> 12 months post-intervention); BITSEA, Brief Infant Toddler Social Emotional Assessment; ASQ:SE, Ages & Stages Questionnaires: Social-Emotional; CBCL, Child Behavior Checklist; ITSEA, Infant Toddler Social Emotional Assessment; DECA, Devereux Early Childhood Assessment; MDI, Mental Developmental Index; PDI, Psychomotor Development Index; CFI, Concept Familiarity Index; PLS-3, Preschool Language Scale; SDQ, Strengths and Difficulties Questionnaires; CGAS, Children's Global Assessment Scale

Meta-analysis of the primary outcome is reported in figure 2, secondary outcomes in online figures.

Figure 2 about here

Behavior

The meta-analysis of parent-reported child behavior shown in figure 2 included eight studies.[34,43,46,50,53,56,57] The analysis showed a small but significant effect on child behavior ($d=0.14$; 95% CI: 0.026 to 0.26) favoring the intervention group. One study that offered a considerably longer intervention than the rest was removed for a sensitivity analysis, which found that the results were not substantially affected by removing the study.[34] The study was therefore kept in the analysis. For the internalizing and externalizing subscales, no significant difference between intervention and control group was found (see online figure 1 and 2). None of the behavioral outcomes that were not included in a meta-analysis showed significant differences between intervention and control group.[44,53,57]

Three studies reported observer-rated child behavior using the behavioral rating scale (BRS) from Bayley II.[44,53,57] One study used a dichotomized version of BRS,[44] which may not have been able to detect changes in this population since all but one (intervention) and three (control) children were rated as unproblematic. Meta-analysis was therefore not conducted. None of the studies found significant effects.

Cognitive development

The meta-analysis on cognitive development included five studies (online figure 3).[44–46,53,58] There was no significant difference between intervention and control groups ($d=0.13$; 95% CI: -0.08 to 0.41). A sensitivity analysis was conducted in which the one study that did not apply the MDI was removed, [45] and the analysis found that the effect size decreased ($d=0.03$) but remained insignificant (95% CI: -0.12 to 0.21).

Psychomotor development

We could not perform meta-analysis for psychomotor development outcomes, as one study provided data comparing two active interventions.[40] Of the three studies that included psychomotor development, none of them found significant effects.[40,44,53]

Communication/language development

We could not perform meta-analysis for communication/language outcomes, as the measures varied considerably. Two studies found no significant effect on communication/language development,[46,53] whereas one found significantly improved communication/language development for the intervention group ($d=0.72$; 95% CI: 0.24 to 1.20).[45]

Child development outcomes at follow-up

Because few studies reported child development outcomes at follow-up, we were only able to conduct a meta-analysis for one of the follow-up outcomes.

Child behavior

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The meta-analysis of parent-rated child behavior at long-term follow-up, as shown in online figure 4, included child behavior scores (SDQ) from three studies.[34,51,56] No significant effect was found ($d=0.15$; 95% CI: -0.03 to 0.31).

At short-term follow-up, one study found a significant positive effect on child behavior ($d=1.05$; 95% CI: 0.47 to 1.62).[43] At medium-term follow-up, one study found no significant effects on behavioral concerns, conduct problems, hyperactivity, or peer problems.[34] At long-term follow-up, one study found a significant positive effect on child functioning (CGAS) ($d=0.69$; 95% CI: 0.17 to 1.21),[51] and one study found a significant positive effect on child socio-emotional development (DECA) (OR=2.44; 95% CI: 1.10 to 6.25).[34]

No studies reported follow-up data on cognitive development, communication/language, or psychomotor development.

Parent–child relationship at post-intervention

Table 5 presents the study outcomes for the individual studies.

Table 5 Parent-child relationship outcomes as reported across studies included in the systematic review

Study	Measure	Assess- ment	Child age (months)	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
Ammaniti et al. 2006[54]	Sensitivity (M) (homemade)	V	12	45	7.25	1.06	37	6.67	1.31	0.49(0.05;0.93)	
	Cooperation (D) (homemade)	V	12	45	8.11	0.94	37	7.67	1.19	0.42(-0.02;0.85)	
	Interference (M) (homemade) ○	V	12	45	1.36	0.81	37	1.52	0.80	0.20(-0.24;0.63)	
	Affective state (M) (homemade) ○	V	12	45	1.15	0.44	37	1.39	0.66	0.44(-0.00;0.88)	
	Self-regulative behaviors (C) (homemade)	V	12	45	1.92	0.95	37	1.96	0.99	-0.04(-0.48;0.39)	
Baggett et al. 2010[41]	Positive behaviors (C) Landry	V	~10	20			20			0.69(0.05;1.33)	Eta ² =0.107
	Positive behaviors (P) Landry	V	~10	20			20			0.45(-0.17;1.08)	Eta ² =0.049
Barlow et al. 2007[57]	Sensitivity (M) CARE-index	V	12	62	9.27	2.67	59	8.2	3.26	0.36(0.00; 0.72)	
	Cooperativeness (C) CARE-index	V	12	62	9.35	3.08	59	7.92	3.7	0.42(0.06;0.78)	
Bridgeman et al. 1981, New Orleans, Louisiana[45]	Positive Language (M) Homemade	V	36	42	30.26	27.07	31	7.24	39.93	0.70(0.22;1.17)	
	Sensitivity (M) Ainsworth's rating scale	V	36	42	6.29	1.62	31	5.19	2.30	0.57(0.09;1.04)	
	Acceptance (M) Ainsworth's rating scale	V	36	42	6.87	1.31	31	6.52	1.55	0.25(-0.22;0.71)	
	Cooperation (M) Ainsworth's rating scale	V	36	42	6.03	1.96	31	5.48	1.98	0.28(-0.19;0.75)	
Høivik et al. 2015[43]	EAS ○	V	~9-10	73	151.90	19.6	52	145.84	29.24	0.25(-0.11;0.61)	
Salomonsson et al 2015b[52]	Sensitivity (M) EAS	V	~11	38	0.64	0.13	37	0.57	0.17	0.46(0.00;0.92)	
	Structuring (M) EAS	V	~11	38	0.71	0.12	37	0.68	0.16	0.21(-0.24;0.67)	
	No intrusiveness (M) EAS	V	~11	38	0.78	0.16	37	0.73	0.23	0.25(-0.20;0.71)	
	Responsiveness (C) EAS	V	~11	38	0.70	0.13	37	0.67	0.20	0.18(-0.28;0.63)	
	Involvement (C) EAS	V	~11	38	0.69	0.14	37	0.66	0.19	0.18(-0.27;0.63)	
van den Boom et al. 1994[47]	Interactive behavior (M) (homemade)	V	9	~47			~47			1.78(1.30;2.26)	
	Interactive behavior (C) (homemade)	V	9	~47			~48			1.54(1.08;2.00)	
Velderman et al. 2006[49]	Sensitivity (M) Ainsworth's rating scale	V	11-13	54			27			0.48(0.02;0.95) ◇	
Sierau et al. 2015[53]	Affectivity (D) MBRS-R	V	24	146	3.16	0.61	142	3.35	0.63	-0.31(-0.54; -0.07)	
	Responsiveness (D) MBRS-R	V	24	145	3.38	0.70	140	3.54	0.68	-0.23(-0.46;0.00)	
Taylor et al. 1997[40]	NCATS	V	~15	50	59.5	6.1	50	59.4	6.0	0.00(-0.39;0.39) ▲	
SF	Parent-child relationship										
Høivik et al. 2005[43]	EAS○	V	~15-16	63	153.40	22.33	47	156.15	19.25	0.13(-0.25;0.51)	
MF	Parent-child relationship										
van den Boom et al. 1995[48]	Acceptance (M) Based on Ainsworth	V	18	43	6.86	1.19	39	5.95	1.88	0.58(0.14;1.03)	F=7.04
	Accessibility (M) Based on Ainsworth	V	18	43	6.88	1.50	39	5.87	1.89	0.60(0.15;1.04)	F=7.26
	Cooperation (M) Based on Ainsworth	V	18	43	6.70	1.68	39	5.18	1.65	0.91(0.46;1.37)	F=16.92

Study	Measure	Assess ment	Child age (months)	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
	Sensitivity (M) Based on Ainsworth	V	18	43	6.70	1.42	39	5.26	1.92	0.86(0.41;1.31)	$F=15.14$
LF	Parent-child relationship										
Salomonsson et al 2015b[52]	Sensitivity (M) EAS	V	54	33	0.68	0.12	33	0.67	0.16	0.07(-0.41;0.55)	
	Structuring (M) EAS	V	54	33	0.66	0.12	33	0.69	0.13	-0.24(-0.72;0.24)	
	No Intrusiveness (M) EAS	V	54	33	0.82	0.12	33	0.81	0.14	0.08(-0.406;0.56)	
	Responsiveness (C) EAS	V	54	33	0.69	0.19	33	0.74	0.15	-0.29(-0.78;0.19)	
	Involvement (C) EAS	V	54	33	0.67	0.13	33	0.72	0.16	-0.34(-0.83;0.14)	
PI	Attachment										
Cassidy et al. 2011[42]	Attachment SSP	V	12	85			84			0.30(-0.06;0.66) χ^2	B=0.54 (SE=0.33) OR=1.72(0.90;3.28) \square
Velderman et al. 2006[49]	Attachment SSP	V	13	54			27			0.22(-0.22;0.66)	
SF	Attachment										
van den Boom et al. 1994[47]	Attachment SSP	V	12	50			50			0.97(0.48;1.45) χ^2	Secure/insecure: Intervention:31/9, control:11/39. OR= 5.78 (2.40;13.94) . $L^2(1)=16.96$
MF	Attachment										
van den Boom et al. 1995[48]	Attachment SSP	V	18	43			39			1.07(0.58;1.57) χ^2	$\chi^2=18.35$
LF	Attachment										
Salomonsson et al 2015a[51]	Secure Attachment SSAP	V	54	31	2.22	1.05	30	2.32	1.33	-0.08(-0.59;0.42)	
	Avoidant Attachment SSAP \circ	V	54	31	1.05	0.48	30	1.16	0.52	0.22(-0.28;0.72)	
	Ambivalent Attachment SSAP \circ	V	54	31	0.96	0.73	30	0.84	0.61	-0.18(-0.68;0.32)	
	Disorganized Attachment SSAP \circ	V	54	31	0.80	0.84	30	0.63	0.58	-0.23(-0.74;0.27)	

χ^2 Calculation based on dichotomous outcome

\circ Reverse scoring – high score is negative

\diamond Adjusted for pretest sensitivity

\square Adjusted for income, infant sex and irritability

\blacktriangle No control group. Two interventions were compared.

U, unadjusted; Q, questionnaire; O, observation; V, video; M, mother; C, child; PI, post-intervention; SF, short-term follow-up (≤ 6 months post intervention); MF, mid-term follow-up (7-12 months); LF, long-term follow-up (>12 months post-intervention); CARE, Child-Adult Relationship Experimental; EAS, Emotional Availability Scales; NCATS, Nursing Child Assessment Teaching Scale; SSP, Strange Situation Procedure; SSAP, Story Stem Assessment Profile

Meta-analysis of the primary outcome is reported in figure 3, secondary outcomes in online figures.

Figure 3 about here

Parent–child relationship

The meta-analysis of the overall parent–child relationship included nine studies and is presented in figure 3.[41,43,45,47,49,52–54,57] The parent–child relationship was significantly better in the intervention group as compared to the control group ($d=0.44$; 95% CI: 0.09 to 0.80). The measures reported in the studies vary to some degree, which could be a source of heterogeneity. I^2 was 80.88, indicating that a large proportion of the observed variance in effect sizes may be attributable to heterogeneity rather than to sampling error.

Maternal sensitivity

We performed a separate meta-analysis on maternal sensitivity, which is a central component in the parent–child relationship. The meta-analysis included five studies (online figure 5) and showed a significant effect favoring the intervention group ($d=0.46$; 95% CI: 0.26 to 0.65).[45,49,52,54,57]

Attachment

Two studies reported attachment classification.[42,49] They found no significant effects of the intervention.

Parent–child relationship at follow-up

Because few studies reported parent–child relationship outcomes at follow-up, we could not conduct meta-analyses for any parent–child relationship follow-up outcomes.

At short-term follow-up, one study found no significant effect on the parent–child relationship.[43] At medium-term follow-up, one study found significant positive effects on maternal acceptance ($d=0.58$; 95% CI: 0.14 to 1.03), accessibility ($d=0.60$; 95% CI: 0.15 to 1.04), and cooperation ($d=0.91$; 95% CI: 0.46 to 1.37).[48] At long-term follow-up, one study did not find a significant effect on the parent–child relationship.[52]

Maternal sensitivity

At medium-term follow-up, one study found a significant positive effect on maternal sensitivity ($d=0.86$; 95% CI: 0.41 to 1.31).[48] At long-term follow-up, one study found no significant effect on maternal sensitivity.[52]

Attachment

At short- and medium-term follow-up, one study found a significant positive effect on attachment at both the 12-month follow-up ($d=0.97$; 95% CI: 0.48 to 1.45) and the 18-month follow-up ($d=1.07$; 95% CI: 0.58 to 1.57).[48,47] At long-term follow up, one study did not find a significant effect on attachment.[51]

Sensitivity analyses

The meta-analysis on the parent–child relationship indicated that substantial heterogeneity may be present. Sensitivity analyses showed that one study in particular contributed to the high I^2 -value.[47] When this study was removed from

the analysis, I^2 and Tau^2 decreased to 47.11 and 0.04 (95% CI: 0.00 to 0.22), respectively. The effect size decreased to 0.26 (95% CI: 0.05 to 0.50).

Two of the studies included in the meta-analyses had outcomes with domains at moderate to high risk of bias.[43,45] Removing Bridgeman et al. (1981) from the meta-analysis on child behavior did not alter the results considerably ($d=0.12$; 95% CI: 0.01 to 0.25). When removed from the analysis on cognitive development, the effect decreased but remained insignificant ($d=0.032$; 95% CI: -0.03 to 0.21). For the parent-child relationship the effect was almost unchanged when Bridgeman et al. (1981) and Høivik et al. (2015) were removed. The effect did, however, approach insignificance ($d=0.47$; 95% CI: 0.00 to 0.95). The effect on maternal sensitivity ($d=0.44$; 95% CI: 0.22 to 0.65) was not altered considerably by removing Bridgeman et al. (1981).

Relative effects

One study compared two active interventions: group and individual.[40] The authors found no difference between the two interventions on cognitive development, psychomotor development, or the parent-child relationship.

DISCUSSION

We identified 19 papers representing 16 trials that investigated the effects of parenting interventions delivered to at-risk parents of infants aged 0–12 months. Due to the variety of outcome measures applied, not all of the 16 included studies were included in the meta-analyses. At post-intervention, we found a small but significant positive effect on overall child behavior, but no significant effects on child cognitive behavior or the child behavior subscales internalizing or externalizing. We found a

medium-sized effect on overall parent–child relationship and maternal sensitivity. Most of the findings from studies that were not represented in the meta-analyses were not statistically significant.

The meta-analyses showed the most pronounced effect sizes for parent–child interaction and maternal sensitivity, whereas the effects on child behavior and cognitive development were either small or not significant. Most interventions provided direct support for how to improve maternal sensitivity and the relationship between parent and child (e.g., Circle of Security [59] and VIPP [60]). Therefore, it seems reasonable that the parent–child relationship and maternal sensitivity can be improved within a relatively short time period, whereas the effects of the interventions on child development may take longer to emerge.[61]

Two studies represented in the meta-analyses were assessed as having a moderate to high risk of bias in one [45] or two [43] domains. As this could potentially affect the credibility of the results, we conducted sensitivity analyses to investigate these studies’ contribution to the effect sizes. However, removing these studies from the analyses did not substantially alter the effects.

The outcomes applied in the individual studies vary and most meta-analyses are based on heterogeneous measures. Although the measures vary, they do measure the same underlying construct and can therefore be meaningfully combined in the meta-analyses. The meta-analyses of parent-child relationship and maternal sensitivity included home-made measures which could potentially affect the results, however, sensitivity analyses showed that removing these outcomes from the analyses did not substantially alter the results and we therefore kept the outcomes in the analyses.

1 The number of studies in the meta-analyses ranged from three to nine. While a meta-
2 analysis on nine studies is fairly reliable, a meta-analysis including only three studies
3 may provide a less accurate estimate of the overall effect.[62] We therefore applied
4 the random-effects model using the profile-likelihood estimator. This has been
5 recommended for meta-analyses with a small number of studies, because it generates
6 wider confidence intervals than the frequently applied DerSimonian-Laird
7 estimator.[33] The results of the meta-analyses including fewer studies should still be
8 interpreted with some caution.
9

10 This review focuses on interventions for adult mothers; studies with young mothers
11 were excluded, including central studies such as the Olds studies of Nurse Family
12 Partnership (NFP).[61] Although teen mothers are an at-risk group, especially since
13 they often face other risk factors such as poverty, low education, and single
14 parenthood, we have not included them in this review. This is mainly because teen
15 mothers are not yet fully developed. We consider the narrower focus on adult
16 mothers to be a strength, because interventions aimed at teen mothers often differ
17 considerably from interventions aimed at adult mothers.
18

19 The included studies were conducted in countries with different levels of service for
20 families with infants; therefore, it may not be possible to reproduce effects in other
21 contexts. The interventions examined in the studies also varied according to
22 approach, intensity, and duration. Both short and extensive interventions were
23 included in all meta-analyses, and we found no apparent tendencies in the results.
24

25 Due to the relatively low number of studies in the meta-analyses, we could not
26 conduct subgroup analyses. Subgroup analyses are important as they provide
27 information about whether the effect of an intervention is modified by certain
28

circumstances or characteristics of the participants. Eight of the included studies reported some kind of subgroup or moderator analyses.[42–47,49,54]

Most of the studies did not address implementation in their design. This presents challenges with regard to assessing outcomes, as results may have been moderated, both positively and negatively, by implementation quality. Of the 16 studies reviewed, four provided information about efforts to support implementation, such as strategies to reduce participant attrition,[44] information about variability in the number of intervention sessions that some families received,[41,44,53] and information on the intervention.[48,47,53] All of the studies could have included more information about the implementation context and the possible moderating factors associated with different strategies. Without more extensive implementation information, replicability remains problematic, particularly in circumstances where implementation supports were not well documented.

A further limitation of the study is that although many studies reported outcomes during the intervention period and post-intervention, only a few reported follow-up data. We were able to perform meta-analysis for one long-term outcome: child behavior measured by the SDQ. The analysis included three studies and found no significant difference between intervention and control groups. Individual study results at different follow-up times were mixed and therefore inconclusive for both child development and the parent–child relationship at long-term follow-up. It is problematic that the studies did not assess long-term outcomes, because it makes it impossible to evaluate the short-, medium-, and long-term effects of the interventions. Conclusions based on post-intervention assessments may be

insufficient to draw firm conclusions about the effectiveness of parenting interventions.

CONCLUSION

This review identified 16 studies that evaluated the effects of parenting interventions for at-risk caregivers with infants aged 0–12 months on child development and the parent–child relationship. Meta-analyses revealed a small but significant effect on child behavior as well as moderate effects on the parent–child relationship and maternal sensitivity. There were no effects on cognitive development, internalizing behavior, or externalizing behavior at post-intervention, nor were any effects found on child behavior at long-term follow-up. Parenting interventions initiated in the child’s first year of life seem to have the potential to improve child behavior and the parent–child relationship post-intervention.

Few studies assessed child development and parent-child relationship outcomes at follow-up; therefore, it remains unclear whether parenting interventions delivered in this population will have lasting effects. Future studies should incorporate follow-up assessments to examine the long-term effects of early interventions.

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ACKNOWLEDGEMENTS

The authors would like to acknowledge and thank information specialist Anne-Marie Klint Jørgensen and Bjørn Christian Viinholt Nielsen for running the database searches, Rikke Eline Wendt for being involved in the review process, Therese Lucia Friis, Line Møller Pedersen and Louise Scheel Hjorth Thomsen for conducting the screening, and senior researcher Trine Filges and researcher Jens Dietrichson for statistical advice.

CONTRIBUTERS

Signe Boe Rayce co-led the review process, contributed to study design, screening, data extraction, data synthesis, performed risk of bias judgement and meta-analysis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Ida Scheel Rasmussen contributed to study design, contributed to screening, data extraction, data synthesis, performed risk of bias, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Sihu Klest and Joshua Patras contributed to study design, data synthesis, critically revised the manuscript, and approved the final manuscript as submitted.

Maiken Pontoppidan conceptualized and designed the study, co-led the review process, contributed to screening, data extraction, and data synthesis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

COMPETING INTERESTS: The authors state that they have no conflicting interests.

FUNDING: Signe Boe Rayce and Ida Scheel Rasmussen were supported by a grant from the Danish Ministry of Social Affairs and the Interior. Maiken Pontoppidan was supported by the Danish Ministry of Social Affairs and the Interior and grant number 7-12-0195 from TrygFonden.

FINANCIAL DISCLOSURE: The authors have no financial relationships relevant to this article to disclose.

DATA SHARING STATEMENT: No additional data are available

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Table 5 Parent-child relationship outcomes as reported across studies included in the systematic review

Online table 1 Risk of Bias of included studies for child development and parent-child relationship outcomes

Online figure 1 Meta-analysis of studies reporting internalizing behavior at post-intervention

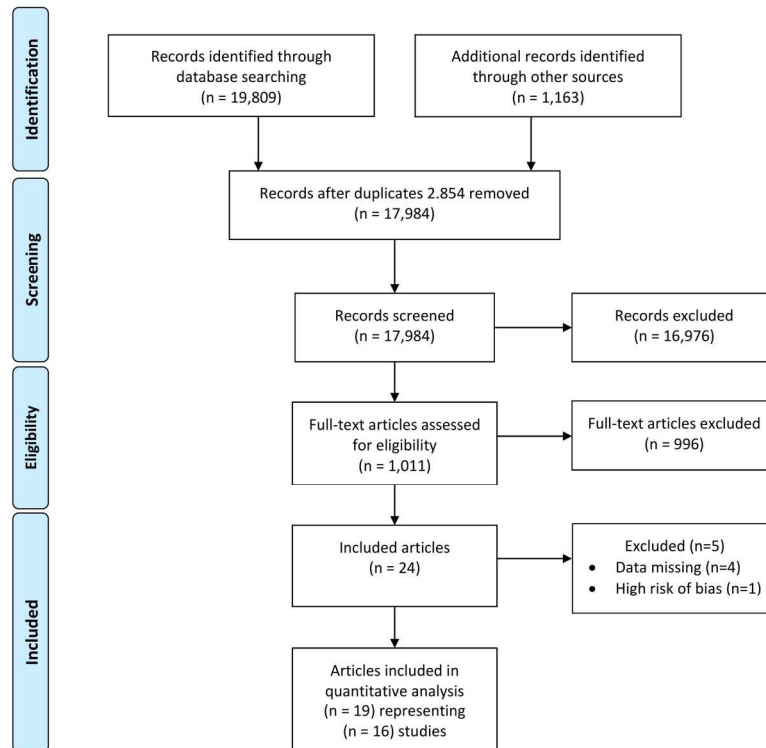
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Online figure 4 Meta-analysis of studies reporting child behavior outcomes at long-term follow up

Online figure 5 Meta-analysis of studies reporting maternal sensitivity outcomes at post-intervention

Figure 1 Flow diagram for study selection process



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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Figure 1 Flow diagram for study selection process

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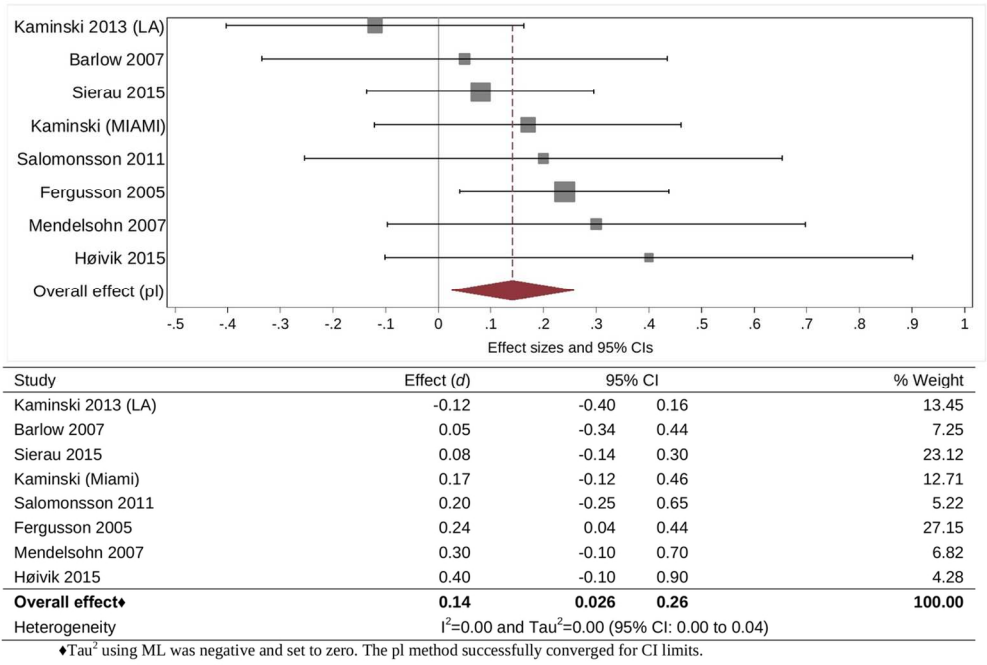


Figure 2 Meta-analysis of studies reporting child behavior outcomes at post-intervention

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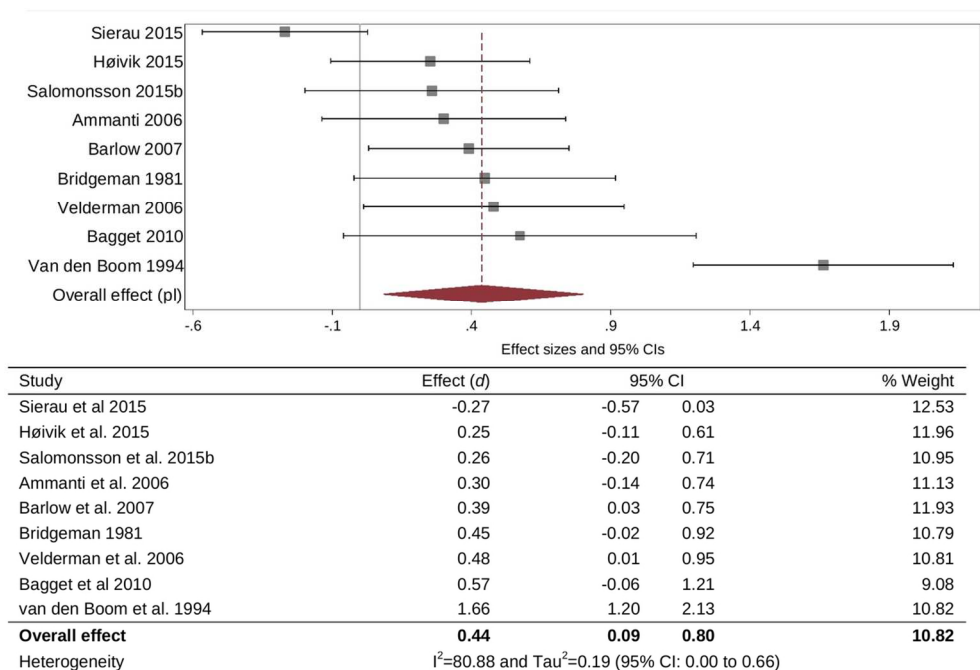


Figure 3 Meta-analysis of studies reporting parent-child relationship outcomes at post-intervention

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Online Table 1 Risk of Bias of included studies for child development and parent-child relationship outcomes

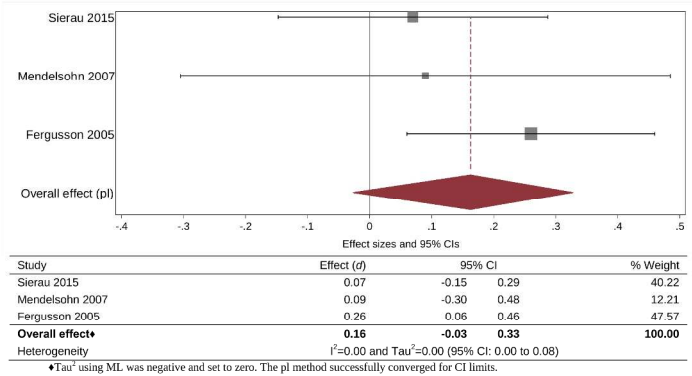
		Sequence generation	Allocation concealment	Blinding of outcome assessor	Incomplete outcome data	Free of selective reporting	A priori protocol	Free of other bias
	Outcome measures /Risk of bias domains							
Child development								
Barlow et al. 2006		L	L	-	-	-	U	-
	BITSEA/ Competence/Problems (Child behavior)	-	-	3	1	U	-	3
	BSID-II (Child cognitive and psychomotor development) BRS (Child behavior)	-	-	2	1	U	-	3
Bridgeman 1981		U	U	-	-	-	U	-
	Stanford-Binet (Child cognitive development) CFI (Child cognitive development) Pacific (Child cognitive development) Ammons (Child Communication/language development)	-	-	1	4	U	-	U
Kaminski et al. 2013*	DECA (Child behavior) SDQ (Child behavior)	L	L	3	3	1	Yes	1
Katz et al. 2011	BSID-II (Child cognitive and psychomotor development) BRS Bayley-II (Child behavior)	L	U	U	4	U	U	3
Mendelsohn et al. 2007		L	L	-	-	-	U	-
	BSID-II/MDI (Child cognitive development) PLS-3 (Child Communication/language development)	-	-	1	3	U	-	1
	CBCL/Internalizing/Externalizing/total (Child behavior)	-	-	3	3	U	-	1
Taylor et al. 1997	BSID II (Child cognitive and psychomotor development) CBCL (Child behavior)	L	U	1	3	U	U	1
		-	-	3	2	1	-	1
Fergusson et al. 2005	ITSEA/Externalizing/Internalizing/Total (Child behavior)	L	U	3	2	U	U	2
Fergusson et al. 2013		L	U	-	-	-	U	-
	SDQ (Child behavior - parent-rated)	-	-	3	2	U	-	2
	SDQ (Child behavior – teacher-rated)	-	-	2	2	U	-	2
Høivik et al. 2015	ASQ:SE (Child behavior)	H	H	3	4	1	Yes	U
Salomonsson et al 2011	ASQ:SE (Child behavior)	L	L	3	1	U	U	U
Salomonsson et al 2015a		L	L	-	-	-	U	-
	ASQ:SE (Child behavior) SDQ (Child behavior – parent-reported)	-	-	3	1	U	-	U
	SDQ (Child behavior – teacher-reported)	-	-	2	1	U	-	U
	CGAS (Child behavior)	-	-	1	1	U	-	U
Sierau et al. 2015		L	U	-	-	-	U	-
	BSID II/MDI/PDI (Child cognitive and psychomotor development) BRS Bayley-II (Child behavior) SETK-2 (Child Communication/language)	-	-	1	3	U	-	1
	ELFRA 1 and 2 (Child Communication/language) CBCL/Internalizing/Externalizing (Child behavior)	-	-	3	3	U	-	1

		Sequence generation	Allocation concealment	Blinding of outcome assessor	Incomplete outcome data addressed	Free of selective reporting	A priori protocol	Free of other bias
	Outcome measures /Risk of bias domains							
Parent-child relationship								
Ammaniti et al. 2006	Scales of Mother-Infant Interactional Systems (Parent-child relationship)	U	U	1	U	U	U	1
Bagget et al. 2010	Landry (Parent-child relationship)	U	U	1	1	U	U	1
Barlow et al. 2006	CARE-Index/ Maternal sensitivity/Infant cooperativeness (Parent-child relationship, maternal sensitivity)	L	L	2	1	U	U	3
Bridgeman 1981*	Mother-child relationship (based on Ainsworth) (Parent-child relationship)	U	U	1	4	U	U	U
Cassidy et al. 2013	SSP (Mother-Infant attachment)	U	U	1	1	U	Yes	1
Velderman et al 2006*	Maternal sensitivity (Ainsworth) (Maternal sensitivity) SSP (Mother-Infant attachment)	U	U	1	1	U	U	3
Taylor et al. 1997	NCATS (Parent-child relationship)	L	U	1	3	U	U	1
van den Boom 1994*	Maternal interactive behavior (Parent-child relationship) Infant interactive behavior (Parent-child relationship) SSP (Mother-Infant attachment)	U	U	1	U	U	U	1
van den Boom 1995*	SSP (Mother-Infant attachment) Mother-child interaction (based on Ainsworth)(Parent-child relationship, maternal sensitivity)	U	U	1	2	1	U	1
Høivik et al. 2015	EAS (Parent-child relationship)	H	H	1	2	1	Yes	U
Salomonsson et al 2015b		L	L	-	-	-	U	-
	SSAP (Mother-Infant attachment)	-	-	1	1	U	-	U
	EAS (Parent-child relationship)	-	-	1	U	U	-	2
Sierau et al. 2015	MBRS revised/Affectivity/Responsiveness (Parent-child relationship)	L	U	1	3	U	U	1

*Note: Risk of bias was conducted for each outcome. When risk of bias was the same for all included outcomes, only one score is provided in the table.

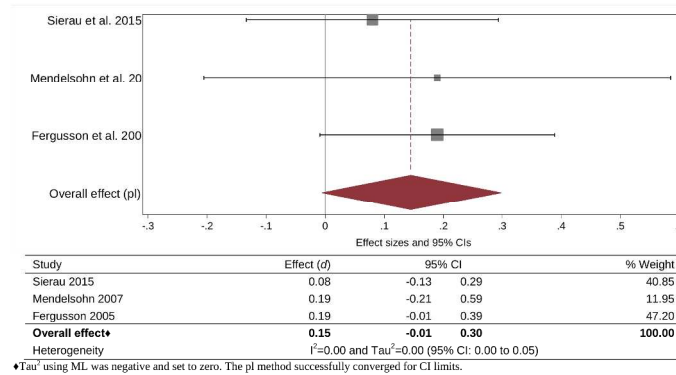
Note: In the 5-point scale 1 corresponds to low risk of bias and 5 correspond to high risk of bias. L= low risk of bias; H=high risk of bias; U= unclear risk of bias

Ammons: Ammons full range picture vocabulary test, ASQ:SE: Ages and Stages Questionnaires: Social Emotional, BITSEA: Brief Infant Toddler social and emotional assessment, BRS Bayley-II: Behavior Rating Scale, BSID-II: Bayley Scales of Infant Development, CBCL: Child Behavior Checklist, CFI: Concept Familiarity Index, CGAS: Children's Global Assessment Scale, DECA: The Devereux Early Childhood Assessment, EAS: Emotional availability scales, ELFRA 1 and 2: Elternfragebögen für die Früherkennung von Risikokindern, ITSEA: Infant Toddler social and emotional assessment, Landry: The Landry Parent-Child Interaction Scales, MBRS revised: Maternal behavior rating scale, NCATS: The nursing child assessment teaching scale, Pacific: Meyers Pacific Test Series, PLS-3: Preschool language scale-3, SDQ: Strengths and Difficulties Questionnaire, SETK-2: Sprachentwicklungstest für zweijährige Kinder, SSAP: Story Stem Assessment Profile, SSP: Strange situation procedure, Stanford-Binet: Stanford-Binet Intelligence Scales



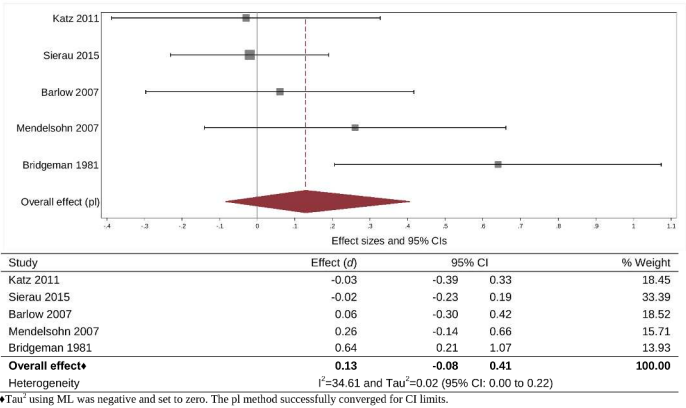
Online figure 1 Meta-analysis of studies reporting internalizing behavior at post-intervention

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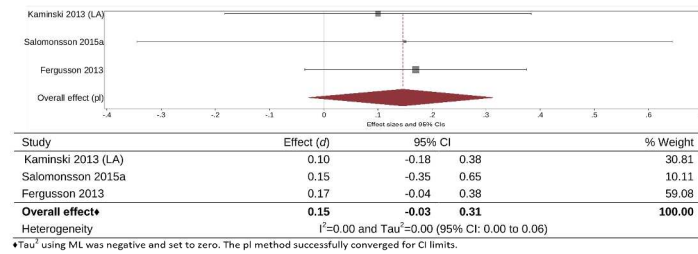
Online figure 2 Meta-analysis of studies reporting externalizing behavior at post-intervention

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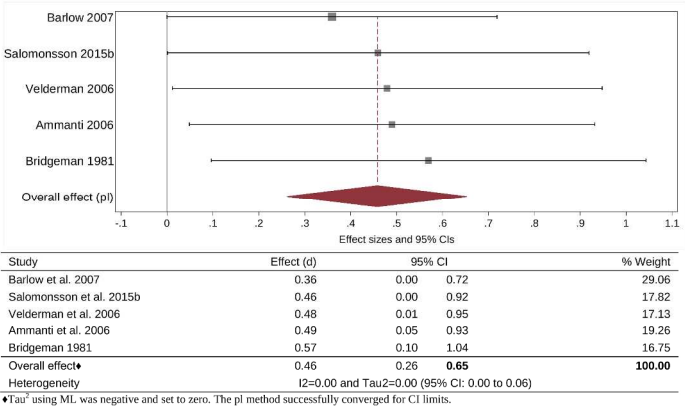
Online figure 3 Meta-analysis of studies reporting cognitive development outcomes at post-intervention

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Online figure 4 Meta-analysis of studies reporting child behavior outcomes at long-term follow up

297x420mm (300 x 300 DPI)



Online figure 5 Meta-analysis of studies reporting maternal sensitivity outcomes at post-intervention

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(experiment* AND design*) or (experiment* AND method*) or (experiment* AND stud*) or (experiment* AND evaluation*) or (experiment* AND test*) or (experiment* AND assessment*) or "assessment only" or "comparison sample" or propensity-matched or (between AND group*) or longi-tud*)[Title/Abstract])) OR (((Non-random* or nonradom* or (non AND random*)) [Title/Abstract])) OR (((control or treatment or experiment* or intervention or assign*) AND (group* or subject* or patient* or intervention)) [Title/Abstract])) OR rct) OR "Random Allocation"[Title/Abstract]) OR ((randomized controlled trial[MeSH Terms]) OR propensity score[MeSH Terms]) OR (((systematic OR literature[Title/Abstract])) AND review*[Title/Abstract])

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5-6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7 table 1
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6-7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary file
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7 figure 1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7-8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8-9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	8-10



PRISMA 2009 Checklist

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8-9
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 1 Flow diagram
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 2+3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Online table 1
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Tables 4+5
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	20-26, Figure 2-3, Online figure 1-5
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	16-17
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	26-27
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	27-30
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	27-30
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	30-31
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	32



PRISMA 2009 Checklist

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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BMJ Open

The effects of parenting interventions for at-risk parents with infants: A systematic review and meta-analyses

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015707.R2
Article Type:	Research
Date Submitted by the Author:	30-Jun-2017
Complete List of Authors:	Rayce, Signe; Nationale Forskningscenter for Velfard, Child and Family Rasmussen, Ida ; Nationale Forskningscenter for Velfard, Child and Family Klest, Siu; University of Tromsø, The Regional Centre for Child and Youth Mental Health and Child Welfare - North Patras, Joshua; University of Tromsø, The Regional Centre for Child and Youth Mental Health and Child Welfare - North Pontoppidan, Maiken; Nationale Forskningscenter for Velfard, Child and Family
Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	General practice / Family practice, Paediatrics, Public health
Keywords:	PAEDIATRICS, Community child health < PAEDIATRICS, PRIMARY CARE, Child & adolescent psychiatry < PSYCHIATRY, PUBLIC HEALTH, Clinical trials < THERAPEUTICS

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The effects of parenting interventions for at-risk parents with infants: A systematic review and meta-analyses

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Word count: 4489

Keywords: Child development, infant development, parent-child relationship, parenting intervention, systematic review.

ABSTRACT

Objectives: Infancy is a critical stage of life, and a secure relationship with caring and responsive caregivers is crucial for healthy infant development. Early parenting interventions aim to support families in which infants are at risk of developmental harm. Our objective is to systematically review the effects of parenting interventions on child development and on parent–child relationship for at-risk families with infants aged 0–12 months.

Design: A systematic review and meta-analyses. We extracted publications from 10 databases in June 2013, January 2015, and June 2016, and supplemented with grey literature and hand search. We assessed risk of bias, calculated effect sizes, and conducted meta-analyses.

Inclusion criteria: 1) Randomized controlled trials of structured psychosocial interventions offered to at-risk families with infants aged 0–12 months in Western OECD countries, 2) Interventions with a minimum of three sessions and at least half of these delivered postnatally, and 3) Outcomes reported for child development or parent–child relationship.

Results: Sixteen studies were included. Meta-analyses were conducted on seven outcomes represented in 13 studies. Parenting interventions significantly improved child behavior ($d=0.14$; 95% CI: 0.03 to 0.26), parent–child relationship ($d=0.44$; 95% CI: 0.09 to 0.80), and maternal sensitivity ($d=0.46$; 95% CI: 0.26 to 0.65) post-intervention. There were no significant effects on cognitive development ($d=0.13$; 95% CI: -0.08 to 0.41), internalizing behavior ($d=0.16$; 95% CI: -0.03 to 0.33), or externalizing behavior ($d=0.16$; 95% CI: -0.01 to 0.30) post-intervention. At long-term follow-up we found no significant effect on child behavior ($d=0.15$; 95% CI: -0.03 to 0.31).

Conclusions: Interventions offered to at-risk families in the first year of the child's life appear to improve child behavior, parent–child relationship, and maternal sensitivity post-intervention, but not child cognitive development, internalizing, or externalizing behavior. Future studies should incorporate follow-up assessments to examine long-term effects of early interventions.

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Strengths and limitations of this study:

- Comprehensive search strategy and screening procedure
- Evaluation of child development and parent–child relationship outcomes
- Meta-analyses conducted on seven outcomes
- Few studies provide follow-up data
- Limited information on intervention implementation

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INTRODUCTION

The first year of a child's life is characterized by rapid development that forms the foundation for lifelong developmental trajectories. A healthy environment is crucial for infants' emotional well-being and future physical and mental health.[1,2]

Experiencing severe adversity early in life can alter a child's development and lead to toxic stress responses, impairing brain chemistry and neuronal architecture.[3] For infants, severe adversity typically takes the form of caregiver neglect and physical or emotional abuse. The highest rates of child neglect and violent abuse occur for children younger than five,[4,5] with the most severe cases, which involve injury or death, occurring predominantly to children under the age of one.[6]

Mental health problems are common in infants, but symptoms are often less intrusive and less distinctly identifiable than for older children.[7–12] The Copenhagen Child Cohort study (CCC2000) found a prevalence rate of 18% for axis I diagnoses (according to DC: 0–3) in children aged 18 months, with regulatory disorders and disturbances in parent child–relationships being the most frequent mental health diagnoses.[8] The high prevalence in mental health diagnoses is important to note, as early onset of behavioral or emotional problems and adverse environmental factors increases the risk for negative outcomes later in life, such as substance abuse, delinquency, violence, teen pregnancy, school dropout, continued mental health problems, and long-term unemployment.[1,2,8,13–18]

Becoming a parent can be stressful and challenging,[19–21] particularly for parents who have experienced trauma, abuse, poverty, or other stressors.[22] Early-intervention parenting programs aim to assist parents with the challenges they experience. Most of these interventions teach caregivers specific strategies and skills

that foster healthy child development with an emphasis on promoting warm and responsive caregiving.[23]

Existing systematic reviews of the effects of parenting interventions offered to families with young children have shown mixed results.[14,24–29] In a review of 78 studies aimed at families with children aged 0–5 years, Piquero et al. found an average effect size (*g*) of 0.37 for decreased antisocial behavior and delinquency for intervention children.[14] Based on 22 studies, Barlow et al. concluded that there is tentative support for the effect of group-based interventions on emotional and behavioral adjustment in children aged 0–3 years.[28] Macbeth et al. found medium effect sizes for child or parent outcomes in a review of the Mellow Parenting intervention for families with children aged 0–8 years.[24] Barlow et al. found some evidence suggesting that parenting programs for teenage parents may improve parent–child interaction.[26] Barlow et al. reviewed parent–infant psychotherapy for high-risk families with infants aged 0–24 months; they found that infant attachment improved, but they found no effects on other outcomes.[27] Reviewing interventions offered to a universal group of parents of infants aged 0–1 year, Pontoppidan et al. found mixed and inconclusive results for child development and parent–child relationship outcomes.[25] Peacock et al. examined the effects of home visits for disadvantaged families with children aged 0–6 years and found improved child development outcomes when the intervention was implemented early.[30]

The existing reviews include very few studies of interventions for at-risk parents that are initiated within the first year of the infants’ life. Therefore, we do not know if early preventive parenting interventions are effective in improving child development or parent–child relationship outcomes. The aim of this review was to

systematically review the effects of parenting interventions offered to at-risk families with infants aged 0–12 months. We included randomized controlled trials of parenting interventions reporting child development or parent–child relationship outcomes at post-intervention or follow-up.

METHODS

Search strategy

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We did not register a protocol. The database searches were performed in June 2013 and were updated in January 2015 and June 2016. We searched ten international bibliographic databases: Campbell Library, Cochrane Library, CRD (Centre for Reviews and Dissemination), ERIC, PsycINFO, PubMed, Science Citation Index Expanded, Social Care Online, Social Science Citation Index, and SocIndex. Operational definitions were determined for each database separately. The main search was made up of combinations of the following terms: infant*, neonat*, parent*, mother*, father*, child*, relation*, attach*, behavi*, psychotherap*, therap*, intervention*, train*, interaction, parenting, learning, and education. The searches included Medical Subject Headings (MeSH), Boolean operators, and filters. Publication year was not a restriction. Furthermore, we searched for grey literature, hand searched four journals, and snowballed for relevant references.

Eligibility criteria and study selection

We screened all publications based on title and abstract. Publications that could not be excluded were screened based on the full-text version. Table 1 shows the inclusion and exclusion criteria.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Population	
At-risk population of parents of infants 0-12 months old in western OECD countries	Studies including specific groups such as young mothers (mean age <20 years), divorced parents, parents with mental health problems such as schizophrenia and abuse and children born pre-term, at low birth weight or with congenital diseases.
Intervention	
Structured psychosocial parenting intervention consisting of at least three sessions and initiated either antenatal or during the child's first year of life with at least half of the sessions delivered postnatally.	Interventions not focusing specifically on parenting (e.g. baby massage, reading sessions with child, or breastfeeding interventions), and unstructured interventions (e.g. home visits not offered in a structured format).
Control group	
No restrictions were imposed. All services or comparison interventions received or provided to the control group were allowed.	
Outcome	
Child development and/or parent-child relationship outcomes	Studies reporting only physical development or health outcomes such as height, weight, duration of breastfeeding, and hospitalization. Papers with insufficient quantitative outcome data to generate standardized mean differences (Cohen's d), odds ratios (OR) and confidence intervals (CI).
Design	
Randomized controlled trials (RCT) or quasi-RCTs.	Other study designs such as case control, cohort, cross sectional, and systematic reviews
Publication type	
Studies presented in peer-reviewed journals, dissertations, books or scientific reports.	Abstracts or conference papers. Studies published in languages others than English, German or the Scandinavian languages (Danish, Swedish and Norwegian).

We excluded studies that examined parenting interventions aimed at specific risk groups such as teen mothers; parents with severe mental health problems; or parents with children born pre-term, at low birth weight, or with congenital diseases. Families experiencing difficulties such as these have specific needs, and interventions aimed at these groups may be more targeted when compared to parenting interventions aimed at broader, at-risk groups of parents. Since our focus

was parenting interventions aimed at at-risk parents in general, we excluded studies developed for specific risk-groups.

Each publication was screened by two research assistants under close supervision by MP and SBR. Uncertainties regarding inclusion were discussed with MP and SBR. Screening was performed in Eppi-Reviewer 4.[31]

Data extraction and risk of bias assessment

We developed a data extraction tool for the descriptive coding and extracted information on 1) study design, 2) sample characteristics, 3) setting, 4) intervention details, 5) outcome measures, and 6) child age at post-intervention and at follow-up. Information was extracted by one research assistant and subsequently checked by another reviewer. Disagreements were discussed with MP or SBR. Primary outcomes were child behavior and the parent–child relationship. Secondary outcomes were other child development markers such as cognitive development, language/communication, psychomotor development, parent sensitivity, and attachment classification. When reported, both total scores and subscale scores were extracted.

Numeric coding of outcome data was conducted by ISR and checked by MP or SBR. We resolved disagreements by consulting a third reviewer. Risk of bias was assessed separately for each relevant outcome for all studies based on a risk-of-bias model developed by Professor Barnaby Reeves and the Cochrane Nonrandomized Studies

Method Group (Reeves, Deeks, Higgins, & Wells, unpublished data, 2011). This extended model is organized and follows the same steps as the existing risk-of-bias model presented in the Cochrane Handbook, chapter 8.[32] The assessment was conducted by ISR and SBR. Any doubts were discussed with a third reviewer.

Analyses

We calculated effect sizes for all relevant outcomes for which sufficient data was provided. Effect sizes were reported using standardized mean differences (Cohen’s *d*) with 95% confidence intervals for continuous outcomes. Data included post-intervention and follow-up means, raw standard deviations, and sample size. Alternatively, *t*-values, *F*-tests, χ^2 , *p*-values, mean differences, eta-square and β -coefficients were used. For dichotomous outcomes, we used odds ratios (ORs) with 95% confidence intervals as the effect size metric when presenting the effects of the individual studies. When used in meta-analyses, ORs were converted to *d* using the method presented in Chin (2000).[33] The data used to calculate ORs were number of events and sample sizes. We contacted the corresponding author for more information if a paper presented insufficient information regarding numeric outcomes. When available, we used data from adjusted analyses to calculate effect sizes. When using the adjusted mean difference, we used the unadjusted standard deviations in order to be able to compare the effect sizes calculated from unadjusted and adjusted means, respectively. To calculate effect sizes, we used the Practical Meta-Analysis Effect Size Calculator developed by David B. Wilson at George Mason University and provided by the Campbell Collaboration.[34]

Meta-analysis was performed when the intervention outcome and the time of assessment were comparable. If a single study provided more than one relevant measure or only subscales for a given meta-analysis, then the effect sizes of the respective measures were pooled into a combined measure.

Random effects inverse variance weighted mean effect sizes were applied and 95% confidence intervals were reported. Studies with larger sample sizes were therefore given more weight, all else being equal. Due to the relatively small number of studies and an assumption of between-study heterogeneity, we chose a random-effects model using the profile-likelihood estimator as suggested in Cornell 2014.[35] Variation in standardized mean difference that was attributable to heterogeneity was assessed with the I^2 . The estimated variance of the true effect sizes was assessed by the Tau^2 statistic. When indication of high heterogeneity ($I^2 > 75\%$) was found, sensitivity analyses were conducted, removing one study at a time in order to identify a potential source of heterogeneity. The small number of studies in the respective meta-analyses did not allow for subgroup analyses. Results were summarized for child development (behavior, cognitive development, psychomotor development, and communication/language) and parent-child relationship (relationship, sensitivity, and attachment classification) outcomes for the following assessment times: post-intervention (PI- immediately after intervention ending), short-term (ST - less than 6 months after intervention ending), medium-term (MT - 7–12 months after intervention ending), and long-term (LT - more than 12 months after intervention ending) follow-up.

RESULTS

Description of studies

The literature search identified 17,984 articles after the removal of duplicates. A flow diagram for the process of study inclusion is illustrated in figure 1. Nineteen papers representing 16 individual studies were included. Kaminski et al. 2013 represented two trials (LA & Miami) and is handled as two studies when reporting results.[36] Four studies were excluded, as they provided insufficient numeric data to calculate effects sizes and CIs.[37–40] One study was excluded due to unacceptably high risk of bias.[41]

Figure 1 about here

Included studies

Except for one study,[42] which compared a group-based intervention to an individual-based intervention, all studies compared interventions to a no-intervention control or to treatment as usual (TAU) . A few studies offered minor interventions such as psychoeducation and social worker contact to the control group.[43–46] Eight studies were American,[36,42–44,46–48]two were conducted in the Netherlands,[49–51] and one study each was from Sweden,[52–54] Germany,[55] Italy,[56] New Zealand,[57,58] Norway,[45] and the United Kingdom.[59] The oldest study was published in 1981[47] and the most recent studies were published in 2015.[45,53–55] Sample size ranged from 40 participants [43] to 755.[55]

Participant characteristics

Table 2 shows study participant characteristics. All families exhibited at least one risk factor such as poverty, low education, or living in deprived areas. Some samples were further characterized by, for example, insecure attachment, risk of developmental delay, or having a difficult or irritable infant. We did not include studies targeting families with more severe problems such as drug abuse, incarceration, or chronic diseases.

Mothers' mean age ranged from 21–33 years. Four studies recruited primiparous mothers,[44,49–51,55] five studies also included mothers with more than one child, [43,45,46,48,52–54] and seven studies did not report parity.[36,42,47,56–59]

Table 2 Participant characteristics

Study	Country	Risk	Mother mean age at start in years	Child age at start in months	Primiparous %	Intervention, n	Control, n
Ammaniti et al[56]	Italy	Depressive or psychosocial risk	33	Third trimester	Not reported	47	44
Baggett et al[43]	USA	Low income	Intervention: 25; Control: 27	~4	Mean number of children: 1.75	20	20
Barlow et al[59]	UK	Vulnerable	< 17 years: Intervention:17.9%; Control:22.2 %	Second trimester	Not reported	68	63
Bridgeman et al[47]	USA	Low income	17 – 35	2	Not reported		Unclear ‡
Cassidy et al[44]	USA	NBAS or low income	24	6.5-9	100	85	84
Fergusson et al[57] & Fergusson et al[58]	New Zealand	Two or more risk factors present	Mother: Intervention: 24; Control: 24 Father: Intervention: 27; Control: 27	Not reported (Recruited within 3 months of birth)	Not reported	206	221
Hoivik et al[45]	Norway	Interactional problems	30	7.3	72	88	70
Kaminski et al[36]	USA	Low income	24	Prenatally (LA), at birth (Miami)	Not reported	338	236
Katz et al[46]	USA	African American with inadequate prenatal care	25	0	Mean number of children: 2.9	146	140
Mendelsohn et al[48]	USA	Low educated latina mothers	Intervention: 30; Control: 30	0.5	Intervention: 21.2; control: 36.2	77	73
Salomonsson et al[52]Salomonsson et al[53] & Salomonsson et al[54]	Sweden	Worried mothers	Intervention: ~34; Control: ~32	Intervention:4.4; Control:5.9	Intervention:81; Control:78	40	40
Sierau et al[55]	Germany	Economic- and social risk factors	Intervention: 21; Control: 22	Third trimester	100	394	361
Taylor et al[42]	USA	Poverty, single marital status, low education, age <20, previous substance abuse, or a history of abuse	Intervention (n): <20: 44, 20-30:122, >30:34; Control: <20:58, 20-30:108, >30:34	3	Not reported	50	50
van den Boom et al[49] & van den Boom et al[50]	Netherlands	Lower-class mothers with irritable infants	Mother: 25 Father: Intervention:28; control:29	6	100	50	50
Velderman et al [51]	Netherlands	Insecure attachment	28	~7	100	54	27

‡ The study only reported number of participants in each analysis

Interventions

Table 3 presents the intervention details. Eight studies offered individual home visits,[44–46,49–51,55–59] three studies offered individual sessions (outside the home),[47,48,52–54] one study offered group sessions,[42] one study offered web-coaching,[43] two studies combined individual sessions and group sessions,[36] and one study combined home visits and group sessions.[46] Intervention was initiated prenatally in four studies,[36,55,56,59] and 12 studies initiated intervention after the child was born.[36,42–54,57,58] The duration of the interventions varied from relatively short interventions (≤ 6 months) [43,44,49–54] to medium-length interventions (7–12 months) [42,45,46,56,59] to long interventions (≥ 24 months).[36,47,48,55,57,58]

Table 3 Intervention characteristics

Study	Name of intervention	N	Intervention				Control	Outcome	
			Begins	Intensity	Format	Ends/duration		Measure	Child age
Ammaniti et al.[56]	Home Visiting Program (HV)	91	8 months pregnant	Weekly and every second week. ~ 36 sessions	Home visits	Ends: 12 months of age	No intervention	Parent-child relationship	12 months
Baggett et al.[43]	Infant Net	40	3-8 months of age	10 online sessions + 1 read to me session + weekly coach calls	Web-coaching	Duration: 6 months	TAU+provided computer and internet technology	Parent-child relationship	~10 months
Barlow et al.[59]	Intervention based on The Family Partnership Model	131	6 months antenatal	Weekly (mean sessions 41.2)	Home visits	Duration: 18 months	TAU	Parent-child relationship Child development	12 months
Bridgeman et al.[47]	Parent Child Development Center (PCDC)	Uncl ear†	2 months of age	Twice a week for a total of six hours	Individual sessions	Ends: 36 months of age	No intervention	Parent-child relationship Child developmentΔ	36 months
Cassidy et al.[44]	Circle of security, home visiting	174	6.5-9 months of age	1 hour every 3 weeks	Home visits	Duration: 3 months	Psychoeducational sessions (3*1 hour)	Parent-child relationshipΔ	12 months
Fergusson et al.[57] & Fergusson et al.[58]	Early Start (2 levels of intensity)	443	Recruited within 3 months of birth	Varied. Low level: up to 2.5 hours per 3 months	Home visits	Duration 36 months	No intervention	Child development	~36 months ~9 years
Høivik et al.[45]	Video feedback, Marte Meo	158	Varies, between 0-24 months of age ~7.3 months of age	8 sessions, 9-13 months (mean 11.5 months)	Home visits	Duration: 9-13 months	TAU + health center nurses if needed	Parent-child relationship Child development	~9-10 months ~15-16 months
Kaminski et al., Los Angeles[36]	Legacy for Children	574	Prenatal in LA	Weekly (2.5 hour) for 3 years in LA	Group sessions and individual sessions	Duration: 3 years in LA	No intervention	Child development	~36 months ~48 months ~60 months
Kaminski et al., Miami [36]	Legacy for Children		At birth in Miami	Weekly (1.5 hour) for 5 years in Miami	Group sessions and individual sessions	Ends: 5 years of age in Miami	No intervention	Child development	~60 months
Katz et al.[46]	Pride in Parenting	286	At birth	Weekly from birth through 4 month and biweekly from 5 to 12	Home visits+groups	Ends: 12 months of age	TAU+monthly contacts from	Child development	12 months

Study	Name of intervention	N	Intervention				Control	Outcome	
			Begins	Intensity	Format	Ends/duration		Measure	Child age
	Program (PIP)			months	sessions		a hospital-based social worker		
Mendelsohn et al.[48]	Video Interaction Project (VIP)	150	2 weeks postpartum	12 sessions (30-45 min. each)	Individual sessions	Ends: 36 months of age	TAU	Child development	33 months
Salomonsson et al.[52], Salomonsson et al[53] & Salomonsson et al[54]	Psychoanalytic treatment	80	Varied: Infants below 1½ years, mean age <6 months	23 session (median), 2-3 hour pr. week	Individual sessions	Duration: Unclear, assumingly 6 months	TAU	Parent-child relationship Child development	4½ years ~11 months ~54 months
Sierau et al[55]	Pro Kind	755	36 gestational weeks (assumingly)	Weekly (first 4 weeks after program intake and 4 weeks after birth), bi-weekly, and monthly (last half year of treatment)	Home visits	Ends: 24 months old (assumingly)	TAU	Parent-child relationship Child development	24 months
Taylor et al[42]	Group well child care (GWCC)	220	3 months of age	7 sessions (45-60 min.) up to 15 months	Group sessions	Ends: ~15 months of age	Individual well child care (IWCC)†	Parent-child relationshipΔ Child developmentΔ	~ 15 months
van den Boom et al[49] & van den Boom et al[50]	-	100	6 months of age (baseline 10 days after birth)	1 sessions (2 hours) every 3 weeks for 3 months	Home visits	Ends: 9 months of child's age	No intervention	Parent-child relationship	9 months 12 months 18 months
Velderman et al[51]	1. VIPP 2. VIPP-R	81	~ 7 months of age	4 visits (1.5-3 hours) over 9-12 weeks	Home visits	Duration: 9 to 12 weeks	No intervention	Parent-child relationship	11-13 months 13 months

TAU: Treatment as Usual

◇ Not a standardized test

† Two active intervention groups, **no** control group

Δ Outcome(s) not included in meta-analysis

Study only reported number of participants in each analysis

Outcomes

Child development and the parent–child relationship were measured based on parent-report questionnaires, teacher-report questionnaires, structured interviews, and videos. Five studies reported only child development outcomes,[36,46,48,57,58] five reported only parent–child relationship outcomes,[43,44,49–51,56] and six reported both.[42,45,47,52–55,59] Timing of assessment was divided into four assessment times: (1) post-intervention follow-up, (2) short-term follow-up, (3) medium-term follow-up, and (4) long-term follow-up.

All studies reported a post-intervention outcome. Two studies reported an outcome at short-term follow-up,[45,49,50] two at medium-term follow-up,[36,49] and three at long-term follow-up.[36,52–54,57,58]

Risk of Bias

The risk of bias assessments are shown in the online table 1 and are divided into child development outcomes and parent-child relationship outcomes. Many studies provided insufficient information for at least two domains, thereby hindering a clear judgment for risk of bias. Risk of bias generally ranged between low and medium. However, three studies had outcomes where one or two domains had a moderate risk of bias.[45–47] Two studies had outcomes with high risk of bias in one domain.[45,47] Based on an overall judgement across risk-of-bias domains, two outcomes (CTBS math and BTBS reading scores) [47] and one study [41] were excluded from the review. The reasons were, on the one hand, high risk of bias in relation to “incomplete data addressed” combined with unclear risk of bias judgements in all other domains,[47] and, on the other hand, the pronounced baseline imbalance not being addressed.[41]

1 The outcomes included in the child development meta-analyses were characterized
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3 by low to medium and unclear risk of bias domains, whereas the meta-analyses on
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5 parent-child relationship outcomes primarily included outcomes with a relatively
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7 low or unclear risk of bias. Two studies represented in the meta-analyses of both
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9 child development and parent-child relationship outcomes had domains assessed as
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11 having moderate or high risk of bias.[45,47]
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14 **Child development outcomes at post-intervention**

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16 Table 4 presents the study outcomes for the individual studies.
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Table 4 Child development outcomes as reported across studies included in the systematic review

Study	Measure	Assess ment	Child age in month s	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
PI	Behavior										
Barlow et al. 2007[59]	Total problem score BITSEA ◯	Q	12	55	33.52	38.81	49	35.55	39.63	0.05(-0.33;0.44)	
	Competence BITSEA	Q	12	53	14.06	3.65	43	13.37	3.53	0.19(-0.21;0.60)	
	BRS	O	12	62	38.37	5.71	59	38.69	5.5	-0.06(-0.41;0.30)	
Høivik et al. 2015[45]	Total score ASQ:SE	Q	~9-10	37			27			0.40(-0.10;0.90)	β=-7.22, SD of DV=18.51 ■
Salomonsson et al. 2011[52]	Total score ASQ:SE ◯	Q	~11	38	1.00	0.72	37	1.14	0.70	0.20(-0.26;0.65)	Becker's δ=0.25(adjusted for baseline ASQ:SE)
Sierau et al. 2015[55]	Internalizing CBCL ◯	Q	24	167	9.51	5.95	159	9.94	5.65	0.07(-0.14;0.29)	
	Externalizing CBCL ◯	Q	24	172	15.93	7.56	164	15.34	7.23	0.08(-0.13;0.29)	
	BRS	O	24	160	53.10	26.74	142	57.13	27.79	-0.15(-0.37;0.08)	
Fergusson et al. 2005[57]	Externalizing ITSEA (short)	Q	~36	207			184			0.19 (-0.01;0.39)	Cohen's d provided in paper
	Internalizing ITSEA (short)	Q	~36	207			184			0.26(0.06;0.47)	Cohen's d provided in paper
	Total problem score ITSEA(50 item)	Q	~36	207			184			0.24(0.04;0.44)	Cohen's d provided in paper
Kaminski et al. 2013, LA[36]	DECA Behavioral concerns	Q	36	126			78			-0.12(-.48;0.25) ✕	OR=0.81 (0.42;1.56)
	DECA Socioemotional problems	Q	36	127			79			-0.04(-0.49;0.43) ✕	OR=0.93(0.41;2.17)
Kaminski et al. 2013, Miami[36]	DECA Behavioral concerns	Q	60	121			73			0.32(-0.07;0.7) ✕	OR=1.78(0.88;3.57)
	DECA Socioemotional problems	Q	60	122			73			0.00(-0.48;0.49) ✕	OR=1.00(0.42;2.44)
	SDQ Conduct problems	Q	60	122			73			0.18(-0.14;0.52) ✕	OR=1.39(0.77; 2.56)
	SDQ Hyperactivity _i	Q	60	121			73			0.31(-0.21;0.84) ✕	OR=1.75(0.69;4.55)
	SDQ Peer problems	Q	60	121			73			-0.14(-.52;0.24) ✕	OR=0.78(0.39;1.54)
Mendelsohn et al. 2007[48]	Total problem score CBCL◯	Q	33	52	50.2	10.0	47	53.2	9.7	0.30(-0.09; 0.70)	
	Externalizing CBCL◯	Q	33	52	50.0	9.8	47	51.8	9.4	0.19(-0.21;0.58)	
	Internalizing CBCL◯	Q	33	52	52.9	9.9	47	53.8	9.3	0.09(-0.30;0.49)	
Katz et al. 2011[46]	BRS	O	12	73			51			0.83(-0.43;2.09) ✕	Normal/non-optimal: Intervention:72/1, control: 48/3, OR=4.5 (0.45; 44.55)
PI	Cognitive development										
Barlow et al. 2007[59]	MDI	O	12	62	93.74	10.98	59	93.03	10.89	0.06(-0.29;0.42)	
Katz et al. 2011 [46]	MDI	O	12	73	101.0	12.4	51	101.4	17.3	-0.03(-0.39;0.33)	
Taylor et al. 1997[42]	MDI	O	~15	50	99.3	14.8	50	100.4	14.3	-0.08(-0.47;0.32) ▲	
Sierau et al. 2015[55]	MDI	O	24	180	87.37	14.74	167	87.64	14.74	-0.02(-0.23;0.19)	
Bridgeman et al. 1981, New Orleans, Louisiana[47]	Intelligence Stanford-Binet	O	36	46	104.22	10.36	52	96.69	12.20	0.66(0.25;1.07)	R=0.49 (incl.all independent variables)
	Concept attainment CFI	O	36	38	33.39	4.69	43	28.02	7.01	0.89(0.43;1.35)	
	Perception Pacific test series	O	36	32	32.09	5.29	42	30.00	6.86	0.34(-0.13;0.80)	
Mendelsohn et al. 2007[48]	MDI	O	33	52	86.1	7.5	45	83.9	9.7	0.26(-0.14;0.66)	

Study	Measure	Assessment	Child age in months	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
PI	Psychomotor development										
Katz et al. 2011[46]	PDI	O	12	73	95.1	13.6	51	93.1	11.9	0.15(-0.20;0.51)	
Taylor et al. 1997[42]	PDI	O	~15	50	103.6	11.5	50	100	12.4	0.30(-0.09;0.70) ▲	
Sierau et al. 2015[55]	PDI	O	24	180	92.86	15.08	167	92.81	14.10	0.00(-0.21;0.21)	
PI	Communication/language										
Bridgeman et al. 1981, New Orleans, Louisiana[47]	Ammons	O	36	34	13.44	3.38	38	11.11	3.09	0.72(0.24;1.20)	
Mendelsohn et al. 2007[48]	PLS-3	O	33	52	80.7	10.2	45	81.1	10.6	-0.04(-0.44;0.36)	
Sierau et al. 2015[55]	ELFRA	O	24	169	102.64	64.69	161	107.84	66.63	-0.08(-0.30;0.14)	
	SETK-2	O	24	141	0.78	0.58	128	0.80	0.61	-0.03(-0.27;0.21)	
SF	Behavior										
Høivik et al. 2015[45]	ASQ:SE	Q	~15-16	26			27			1.05(0.47;1.62)	β=-13.79, SD of DV=15.02 ■
MF	Behavior										
Kaminski et al. 2013 LA[36]	DECA Behavioral concerns	Q	48	124			78			0.26(-0.14;0.66) X	OR=1.61(0.78;333)
	DECA Socioemotional problems	Q	48	124			78			0.00(-0.55;0.55) X	OR=1.00(0.37; 2.70)
	SDQ Conduct problems	Q	48	124			78			0.18(-0.14;0.51) X	OR=1.39 (0.77;2.5)
	SDQ Hyperactivity _i	Q	48	124			78			-0.37(-0.01;0.26) X	OR=0.51(0.16;1.61)
	SDQ Peer problems	Q	48	124			78			-0.12(-0.49;0.26) X	OR=0.81 (0.41;1.61)
LF	Behavior										
Fergusson et al. 2013[58]	SDQ ○	Q	~108	199	9.91	0.91	171	10.08	1.06	0.17(-0.03; 0.38)	
Kaminski et al. 2013 LA[36]	DECA Behavioral concerns	Q	60	116			71			0.27(-0.21;0.72) X	OR=1.62 (0.69;3.70)
	DECA Socioemotional problems	Q	60	117			73			0.49(0.05;1.01) X	OR=2.44 (1.10;6.25)
	SDQ Conduct problems	Q	60	116			71			-0.03(-0.39;0.33) X	OR=0.94 (0.49;1.82)
	SDQ Hyperactivity _i	Q	60	116			71			0.17(-0.37;0.7) X	OR=1.35(0.51;3.57)
	SDQ Peer problems	Q	60	116			71			0.17(-0.24;0.58) X	OR=1.37(0.65;2.86)
Salomonsson et al 2015a[53]	ASQ:SE	Q	54	32	0.98	0.90	32	0.88	0.68	0.13(-0.37; 0.62)	
	SDQ	Q _{parent}	54	32	8.17	5.54	31	7.39	5.19	0.15(-0.35;0.64)	
	SDQ	Q _{teacher}	54	24	5.71	4.32	27	6.59	5.31	-0.18(-0.73; 0.37)	
	CGAS Functioning	Q	54	31	78.39	12.8	30	68.87	14.74	0.69(0.17; 1.21)	

X Calculation based on dichotomous outcome

○ Reverse scoring – high score is negative

■ Adjusted for ASQ baseline score

▲ No control group. Two interventions were compared.

U, unadjusted; Q, questionnaire; O, observation; PI, post-intervention; SF, short-term follow-up (≤6 months post intervention); MF, mid-term follow-up (7-12 months); LF, long-term follow-up (>12 months post-intervention); BITSEA, Brief Infant Toddler Social Emotional Assessment; ASQ:SE, Ages & Stages Questionnaires: Social-Emotional; CBCL, Child Behavior Checklist; ITSEA, Infant Toddler Social Emotional Assessment; DECA, Devereux Early Childhood Assessment; MDI, Mental Developmental Index; PDI, Psychomotor Development Index; CFI, Concept Familiarity Index; PLS-3, Preschool Language Scale; SDQ, Strengths and Difficulties Questionnaires; CGAS, Children's Global Assessment Scale

Meta-analysis of the primary outcome is reported in figure 2, secondary outcomes in online figures.

Figure 2 about here

Behavior

The meta-analysis of parent-reported child behavior shown in figure 2 included eight studies.[36,45,48,52,55,58,59] The analysis showed a small but significant effect on child behavior ($d=0.14$; 95% CI: 0.03 to 0.26) favoring the intervention group. One study that offered a considerably longer intervention than the rest was removed for a sensitivity analysis, which found that the results were not substantially affected by removing the study.[36] The study was therefore kept in the analysis. For the internalizing and externalizing subscales, no significant difference between intervention and control group was found (see online figure 1 and 2). None of the behavioral outcomes that were not included in a meta-analysis showed statistically significant differences between intervention and control group.[46,55,59]

Three studies reported observer-rated child behavior using the behavioral rating scale (BRS) from Bayley II.[46,55,59] One study used a dichotomized version of BRS,[46] which may not have been able to detect changes in this population since all but one (intervention) and three (control) children were rated as unproblematic. Meta-analysis was therefore not conducted. None of the studies found statistically significant effects.

Cognitive development

The meta-analysis on cognitive development included five studies (online figure 3).[46–48,55,60] There was no significant difference between intervention and control groups ($d=0.13$; 95% CI: -0.08 to 0.41). A sensitivity analysis was conducted in which the one study that did not apply the MDI was removed, [47] and the analysis found that the effect size decreased ($d=0.03$) but remained insignificant (95% CI: -0.12 to 0.21).

Psychomotor development

We could not perform meta-analysis for psychomotor development outcomes, as one study provided data comparing two active interventions.[42] Of the three studies that included psychomotor development, none of them found significant effects.[42,46,55]

Communication/language development

We could not perform meta-analysis for communication/language outcomes, as the measures varied considerably. Two studies found no significant effect on communication/language development,[48,55] whereas one found significantly improved communication/language development for the intervention group ($d=0.72$; 95% CI: 0.24 to 1.20).[47]

Child development outcomes at follow-up

Because few studies reported child development outcomes at follow-up, we were only able to conduct a meta-analysis for one of the follow-up outcomes.

Child behavior

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The meta-analysis of parent-rated child behavior at long-term follow-up, as shown in online figure 4, included child behavior scores (SDQ) from three studies.[36,53,58] No significant effect was found ($d=0.15$; 95% CI: -0.03 to 0.31).

At short-term follow-up, one study found a significant positive effect on child behavior ($d=1.05$; 95% CI: 0.47 to 1.62).[45] At medium-term follow-up, one study found no significant effects on behavioral concerns, conduct problems, hyperactivity, or peer problems.[36] At long-term follow-up, one study found a significant positive effect on child functioning (CGAS) ($d=0.69$; 95% CI: 0.17 to 1.21),[53] and one study found a significant positive effect on child socio-emotional development (DECA) (OR=2.44; 95% CI: 1.10 to 6.25).[36]

No studies reported follow-up data on cognitive development, communication/language, or psychomotor development.

Parent–child relationship at post-intervention

Table 5 presents the study outcomes for the individual studies.

Table 5 Parent-child relationship outcomes as reported across studies included in the systematic review

Study	Measure	Assessment	Child age (months)	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
Ammaniti et al. 2006[56]	Sensitivity (M) SMIIS	V	12	45	7.25	1.06	37	6.67	1.31	0.49(0.05;0.93)	
	Cooperation (D) SMIIS	V	12	45	8.11	0.94	37	7.67	1.19	0.42(-0.02;0.85)	
	Interference (M) SMIIS ○	V	12	45	1.36	0.81	37	1.52	0.80	0.20(-0.24;0.63)	
	Affective state (M) SMIIS ○	V	12	45	1.15	0.44	37	1.39	0.66	0.44(-0.00;0.88)	
	Self-regulative behaviors (C) SMIIS	V	12	45	1.92	0.95	37	1.96	0.99	-0.04(-0.48;0.39)	
Baggett et al. 2010[43]	Positive behaviors (C) Landry	V	~10	20			20			0.69(0.05;1.33)	Eta ² =0.107
	Positive behaviors (P) Landry	V	~10	20			20			0.45(-0.17;1.08)	Eta ² =0.049
Barlow et al. 2007[59]	Sensitivity (M) CARE-index	V	12	62	9.27	2.67	59	8.2	3.26	0.36(0.00; 0.72)	
	Cooperativeness (C) CARE-index	V	12	62	9.35	3.08	59	7.92	3.7	0.42(0.06;0.78)	
Bridgeman et al. 1981, New Orleans, Louisiana[47]	Positive Language (M) (In-house)	V	36	42	30.26	27.07	31	7.24	39.93	0.70(0.22;1.17)	
	Sensitivity (M) Ainsworth's rating scale	V	36	42	6.29	1.62	31	5.19	2.30	0.57(0.09;1.04)	
	Acceptance (M) Ainsworth's rating scale	V	36	42	6.87	1.31	31	6.52	1.55	0.25(-0.22;0.71)	
	Cooperation (M) Ainsworth's rating scale	V	36	42	6.03	1.96	31	5.48	1.98	0.28(-0.19;0.75)	
Høivik et al. 2015[45]	EAS ○	V	~9-10	73	151.90	19.6	52	145.84	29.24	0.25(-0.11;0.61)	
Salomonsson et al 2015b[54]	Sensitivity (M) EAS	V	~11	38	0.64	0.13	37	0.57	0.17	0.46(0.00;0.92)	
	Structuring (M) EAS	V	~11	38	0.71	0.12	37	0.68	0.16	0.21(-0.24;0.67)	
	No intrusiveness (M) EAS	V	~11	38	0.78	0.16	37	0.73	0.23	0.25(-0.20;0.71)	
	Responsiveness (C) EAS	V	~11	38	0.70	0.13	37	0.67	0.20	0.18(-0.28;0.63)	
	Involvement (C) EAS	V	~11	38	0.69	0.14	37	0.66	0.19	0.18(-0.27;0.63)	
van den Boom et al. 1994[49]	Interactive behavior (M) (in-house)	V	9	~47			~47			1.78(1.30;2.26)	
	Interactive behavior (C) (in-house)	V	9	~47			~48			1.54(1.08;2.00)	
Velderman et al. 2006[51]	Sensitivity (M) Ainsworth's rating scale	V	11-13	54			27			0.48(0.02;0.95) ◇	
Sierau et al. 2015[55]	Affectivity (D) MBRS-R	V	24	146	3.16	0.61	142	3.35	0.63	-0.31(-0.54; -0.07)	
	Responsiveness (D) MBRS-R	V	24	145	3.38	0.70	140	3.54	0.68	-0.23(-0.46;0.00)	
Taylor et al. 1997[42]	NCATS	V	~15	50	59.5	6.1	50	59.4	6.0	0.00(-0.39;0.39) ▲	
SF	Parent-child relationship										
Høivik et al. 2005[45]	EAS○	V	~15-16	63	153.40	22.33	47	156.15	19.25	0.13(-0.25;0.51)	
MF	Parent-child relationship										
van den Boom et al. 1995[50]	Acceptance (M) Based on Ainsworth	V	18	43	6.86	1.19	39	5.95	1.88	0.58(0.14;1.03)	F=7.04
	Accessibility (M) Based on Ainsworth	V	18	43	6.88	1.50	39	5.87	1.89	0.60(0.15;1.04)	F=7.26
	Cooperation (M) Based on Ainsworth	V	18	43	6.70	1.68	39	5.18	1.65	0.91(0.46;1.37)	F=16.92
	Sensitivity (M) Based on Ainsworth	V	18	43	6.70	1.42	39	5.26	1.92	0.86(0.41;1.31)	F=15.14
LF	Parent-child relationship										

Study	Measure	Assessment	Child age (months)	Intervention				Control				Cohen's d	Other statistics
				n	Mean	SD		n	Mean	SD			
Salomonsson et al 2015b[54]	Sensitivity (M) EAS	V	54	33	0.68	0.12		33	0.67	0.16		0.07(-0.41;0.55)	
	Structuring (M) EAS	V	54	33	0.66	0.12		33	0.69	0.13		-0.24(-0.72;0.24)	
	No Intrusiveness (M) EAS	V	54	33	0.82	0.12		33	0.81	0.14		0.08(-0.406;0.56)	
	Responsiveness (C) EAS	V	54	33	0.69	0.19		33	0.74	0.15		-0.29(-0.78;0.19)	
	Involvement (C) EAS	V	54	33	0.67	0.13		33	0.72	0.16		-0.34(-0.83;0.14)	
PI	Attachment												
Cassidy et al. 2011[44]	Attachment SSP	V	12	85				84				0.30(-0.06;0.66) Δ	B=0.54 (SE=0.33) OR=1.72(0.90;3.28) \square
Velderman et al. 2006[51]	Attachment SSP	V	13	54				27				0.22(-0.22;0.66)	
SF	Attachment												
van den Boom et al. 1994[49]	Attachment SSP	V	12	50				50				0.97(0.48;1.45) Δ	Secure/insecure: Intervention: 31/19, control: 11/39. OR= 5.78 (2.40;13.94) . $L^2(1)=16.96$
MF	Attachment												
van den Boom et al. 1995[50]	Attachment SSP	V	18	43				39				1.07(0.58;1.57) Δ	$\chi^2=18.35$
LF	Attachment												
Salomonsson et al 2015a[53]	Secure Attachment SSAP	V	54	31	2.22	1.05		30	2.32	1.33		-0.08(-0.59;0.42)	
	Avoidant Attachment SSAP \diamond	V	54	31	1.05	0.48		30	1.16	0.52		0.22(-0.28;0.72)	
	Ambivalent Attachment SSAP \diamond	V	54	31	0.96	0.73		30	0.84	0.61		-0.18(-0.68;0.32)	
	Disorganized Attachment SSAP \diamond	V	54	31	0.80	0.84		30	0.63	0.58		-0.23(-0.74;0.27)	

Δ Calculation based on dichotomous outcome
 \diamond Reverse scoring – high score is negative
 \diamond Adjusted for pretest sensitivity
 \square Adjusted for income, infant sex and irritability
 Δ No control group. Two interventions were compared.
U, unadjusted; Q, questionnaire; O, observation; V, video; M, mother; C, child; PI, post-intervention; SF, short-term follow-up (≤ 6 months post intervention); MF, mid-term follow-up (7-12 months); LF, long-term follow-up (> 12 months post-intervention); SMIS: Scales of Mother-Infant Interactional System; CARE: Child-Adult Relationship Experimental; EAS: Emotional Availability Scales; NCATS: Nursing Child Assessment Teaching Scale; SSP: Strange Situation Procedure; SSAP: Story Stem Assessment Profile

Meta-analysis of the primary outcome is reported in figure 3, secondary outcomes in online figures.

Figure 3 about here

Parent–child relationship

The meta-analysis of the overall parent–child relationship included nine studies and is presented in figure 3.[43,45,47,49,51,54–56,59] The parent–child relationship was significantly better in the intervention group as compared to the control group ($d=0.44$; 95% CI: 0.09 to 0.80). The measures reported in the studies vary to some degree, which could be a source of heterogeneity. I^2 was 81, indicating that a large proportion of the observed variance in effect sizes may be attributable to heterogeneity rather than to sampling error.

Maternal sensitivity

We performed a separate meta-analysis on maternal sensitivity, which is a central component in the parent–child relationship. The meta-analysis included five studies (online figure 5) and showed a significant effect favoring the intervention group ($d=0.46$; 95% CI: 0.26 to 0.65).[47,51,54,56,59]

Attachment

Two studies reported attachment classification.[44,51] They found no significant effects of the intervention.

Parent–child relationship at follow-up

Because few studies reported parent–child relationship outcomes at follow-up, we could not conduct meta-analyses for any parent–child relationship follow-up outcomes.

At short-term follow-up, one study found no significant effect on the parent–child relationship.[45] At medium-term follow-up, one study found significant positive effects on maternal acceptance ($d=0.58$; 95% CI: 0.14 to 1.03), accessibility ($d=0.60$; 95% CI: 0.15 to 1.04), and cooperation ($d=0.91$; 95% CI: 0.46 to 1.37).[50] At long-term follow-up, one study did not find a significant effect on the parent–child relationship.[54]

Maternal sensitivity

At medium-term follow-up, one study found a significant positive effect on maternal sensitivity ($d=0.86$; 95% CI: 0.41 to 1.31).[50] At long-term follow-up, one study found no significant effect on maternal sensitivity.[54]

Attachment

At short- and medium-term follow-up, one study found a significant positive effect on attachment at both the 12-month follow-up ($d=0.97$; 95% CI: 0.48 to 1.45) and the 18-month follow-up ($d=1.07$; 95% CI: 0.58 to 1.57).[49,50] At long-term follow up, one study did not find a significant effect on attachment.[53]

Sensitivity analyses

The meta-analysis on the parent–child relationship indicated that substantial heterogeneity may be present. Sensitivity analyses showed that one study in particular contributed to the high I^2 -value.[49] When this study was removed from

the analysis, I^2 decreased from 81 to 47. Tau^2 decreased from 0.19 (95% CI: 0.00 to 0.66) to (95% CI: 0.00 to 0.22). The effect size decreased to 0.26 (95% CI: 0.05 to 0.50).

Two of the studies included in the meta-analyses had outcomes with domains at moderate to high risk of bias.[45,47] Removing Bridgeman et al. (1981) from the meta-analysis on child behavior did not alter the results considerably ($d=0.12$; 95% CI: 0.01 to 0.25). When removed from the analysis on cognitive development, the effect decreased but remained insignificant ($d=0.03$; 95% CI: -0.03 to 0.21). For the parent-child relationship the effect was almost unchanged when Bridgeman et al. (1981) and Høivik et al. (2015) were removed. The effect did, however, approach insignificance ($d=0.47$; 95% CI: 0.00 to 0.95). The effect on maternal sensitivity ($d=0.44$; 95% CI: 0.22 to 0.65) was not altered considerably by removing Bridgeman et al. (1981).

Relative effects

One study compared two active interventions: group and individual.[42] The authors found no difference between the two interventions on cognitive development, psychomotor development, or the parent-child relationship.

DISCUSSION

We identified 19 papers representing 16 trials that investigated the effects of parenting interventions delivered to at-risk parents of infants aged 0–12 months. Due to the variety of outcome measures applied, not all of the 16 included studies were included in the meta-analyses. At post-intervention, we found a small but significant positive effect on overall child behavior, but no significant effects on child cognitive

behavior or the child behavior subscales internalizing or externalizing. We found a medium-sized effect on overall parent–child relationship and maternal sensitivity. Most of the findings from studies that were not represented in the meta-analyses were not statistically significant.

The meta-analyses showed the most pronounced effect sizes for parent–child interaction and maternal sensitivity, whereas the effects on child behavior and cognitive development were either small or not significant, however, small effect sizes can have meaningful impact on population-level outcomes.[61] The non-significant outcomes for internalizing and externalizing behaviors were also small, but may be clinically relevant for large, at-risk populations. Most interventions provided direct support for how to improve maternal sensitivity and the relationship between parent and child (e.g., Circle of Security [62] and VIPP [63]). Therefore, it seems reasonable that the parent–child relationship and maternal sensitivity can be improved within a relatively short time period, whereas the effects of the interventions on child development may take longer to emerge.[64]

The tests for the child behavior subscales internalizing and externalizing narrowly included the zero value within in the 95% CIs (-0.03 to 0.33 and 0.00 to 0.30, respectively). These values suggest that similar studies to those in this review would likely produce small but positive effects. Because these analyses are based on three studies, there is a certain degree of uncertainty regarding the CIs reported. A larger sample of studies may be necessary to conclusively determine the significance of these results.

Two studies represented in the meta-analyses were assessed as having a moderate to high risk of bias in one [47] or two [45] domains. As this could potentially affect the credibility of the results, we conducted sensitivity analyses to investigate these studies' contribution to the effect sizes. However, removing these studies from the analyses did not substantially alter the effects.

The outcomes applied in the individual studies vary and most meta-analyses are based on heterogeneous measures. Although the measures vary, they do measure the same underlying construct and can therefore be meaningfully combined in the meta-analyses.

The meta-analyses of parent-child relationship and maternal sensitivity included in-house measures, that is, measures developed by the evaluators that have, to our knowledge, not been formally validated. This could potentially affect the results, however, sensitivity analyses showed that removing these outcomes from the analyses did not substantially alter the results, therefore, we kept the outcomes in the analyses.

The number of studies in the meta-analyses ranged from three to nine. While a meta-analysis on nine studies is fairly reliable, a meta-analysis including only three studies may provide a less accurate estimate of the overall effect.[65] We therefore applied the random-effects model using the profile-likelihood estimator. This has been recommended for meta-analyses with a small number of studies, because it generates wider confidence intervals than the frequently applied DerSimonian-Laird estimator.[35] The results of the meta-analyses including fewer studies should still be interpreted with some caution.

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This review focuses on interventions for adult mothers; studies with young mothers were excluded, including central studies such as the Olds studies of Nurse Family Partnership (NFP).[64] Although teen mothers are an at-risk group due to their age, and they often face additional risk factors such as poverty, low education, and single parenthood, we have not included them in this review. We believe this is the appropriate method because teen mothers are a distinct group requiring targeted care that is developmentally appropriate for their stage in life. We consider the narrower focus on adult mothers to be a strength, because the interventions aimed at adult mothers most often differ considerably from interventions for teen mothers; this specificity reduces heterogeneity in study outcomes that are often present between the teen and adult interventions.

The included studies were conducted in countries with different levels of service for families with infants; therefore, it may not be possible to reproduce effects in other contexts. The interventions examined in the studies also varied according to approach, intensity, and duration. Both short and extensive interventions were included in all meta-analyses, and we found no apparent tendencies in the results. Due to the relatively low number of studies in the meta-analyses, we could not conduct subgroup analyses. Subgroup analyses are important as they provide information about whether the effect of an intervention is modified by certain circumstances or characteristics of the participants. Eight of the included studies reported some kind of subgroup or moderator analyses.[44–49,51,56]

Most of the studies did not address implementation in their design. This presents challenges with regard to assessing outcomes, as results may have been moderated, both positively and negatively, by implementation quality. Of the 16 studies

reviewed, four provided information about efforts to support implementation, such as strategies to reduce participant attrition,[46] information about variability in the number of intervention sessions that some families received,[43,46,55] and information on the intervention.[49,50,55] All of the studies could have included more information about the implementation context and the possible moderating factors associated with different strategies. Without more extensive implementation information, replicability remains problematic, particularly in circumstances where implementation supports were not well documented.

A further limitation of the study is that although many studies reported outcomes during the intervention period and post-intervention, only a few reported follow-up data. We were able to perform meta-analysis for one long-term outcome: child behavior measured by the SDQ. The analysis included three studies and found no significant difference between intervention and control groups. Individual study results at different follow-up times were mixed and therefore inconclusive for both child development and the parent–child relationship at long-term follow-up. It is problematic that the studies did not assess long-term outcomes, because it makes it impossible to evaluate the short-, medium-, and long-term effects of the interventions. Conclusions based on post-intervention assessments may be insufficient to draw firm conclusions about the effectiveness of parenting interventions.

CONCLUSION

This review identified 16 studies that evaluated the effects of parenting interventions for at-risk caregivers with infants aged 0–12 months on child development and

parent–child relationship. Meta-analyses revealed a small but statistically significant positive effect of the interventions on child behavior as well as moderate effects on the parent–child relationship and maternal sensitivity. There were no statically significant effects on child cognitive development, internalizing behavior, or externalizing behavior at post-intervention; however, internalizing and externalizing behavior were marginally significant and may have reached statistical significance with a larger sample. Similarly, the effect on child behavior at long-term follow-up was not significant, but approaching statistical significance. Parenting interventions initiated in the child’s first year of life appear to have the potential to improve child behavior and the parent–child relationship post-intervention.

Few studies assessed child development and parent-child relationship outcomes at follow-up; therefore, it remains unclear whether parenting interventions delivered in this population will have lasting effects. Future studies should incorporate follow-up assessments to examine the long-term effects of early interventions for at-risk families.

ACKNOWLEDGEMENTS

The authors would like to acknowledge and thank information specialist Anne-Marie Klint Jørgensen and Bjørn Christian Viinholt Nielsen for running the database searches, Rikke Eline Wendt for being involved in the review process, Therese Lucia Friis, Line Møller Pedersen and Louise Scheel Hjorth Thomsen for conducting the screening, and senior researcher Trine Filges and researcher Jens Dietrichson for statistical advice.

CONTRIBUTERS

Signe Boe Rayce co-led the review process, contributed to study design, screening, data extraction, data synthesis, performed risk of bias judgement and meta-analysis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Ida Scheel Rasmussen contributed to study design, contributed to screening, data extraction, data synthesis, performed risk of bias, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Sihu Klest and Joshua Patras contributed to study design, data synthesis, critically revised the manuscript, and approved the final manuscript as submitted.

Maiken Pontoppidan conceptualized and designed the study, co-led the review process, contributed to screening, data extraction, and data synthesis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

COMPETING INTERESTS: The authors state that they have no conflicting interests.

FUNDING: Signe Boe Rayce and Ida Scheel Rasmussen were supported by a grant from the Danish Ministry of Social Affairs and the Interior. Maiken Pontoppidan was supported by the Danish Ministry of Social Affairs and the Interior and grant number 7-12-0195 from TrygFonden.

FINANCIAL DISCLOSURE: The authors have no financial relationships relevant to this article to disclose.

DATA SHARING STATEMENT: No additional data are available

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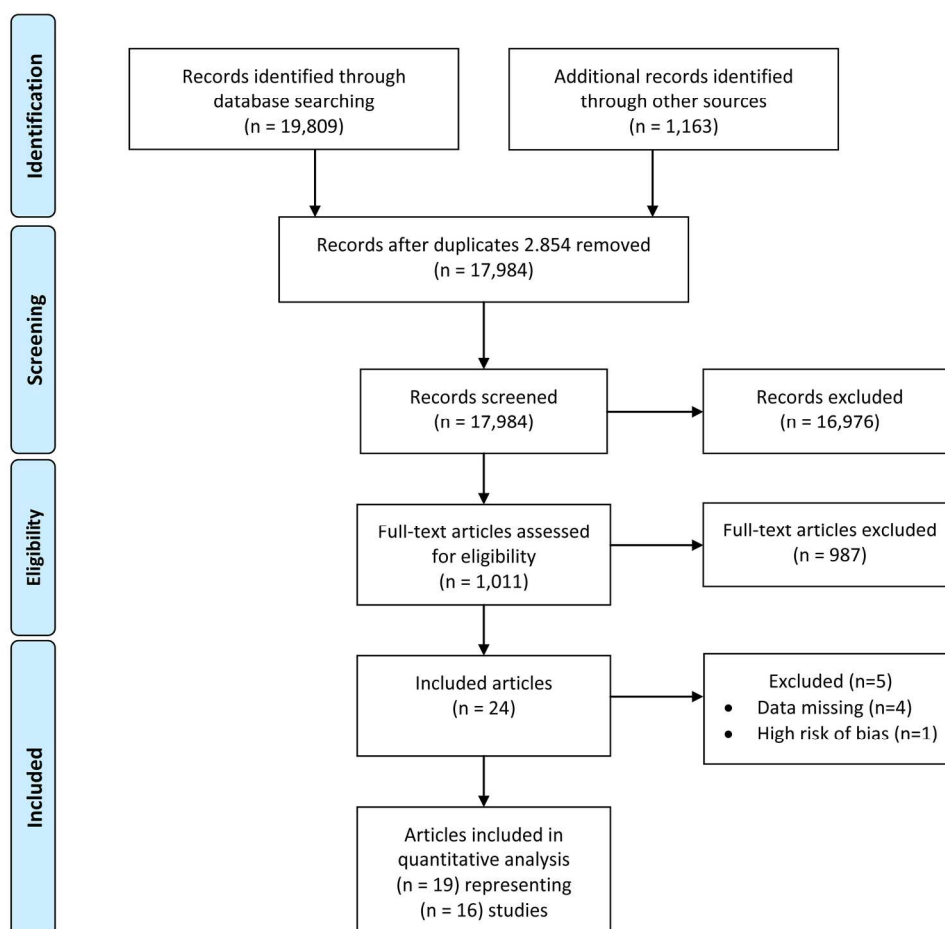


Figure 1 Flow diagram for study selection process

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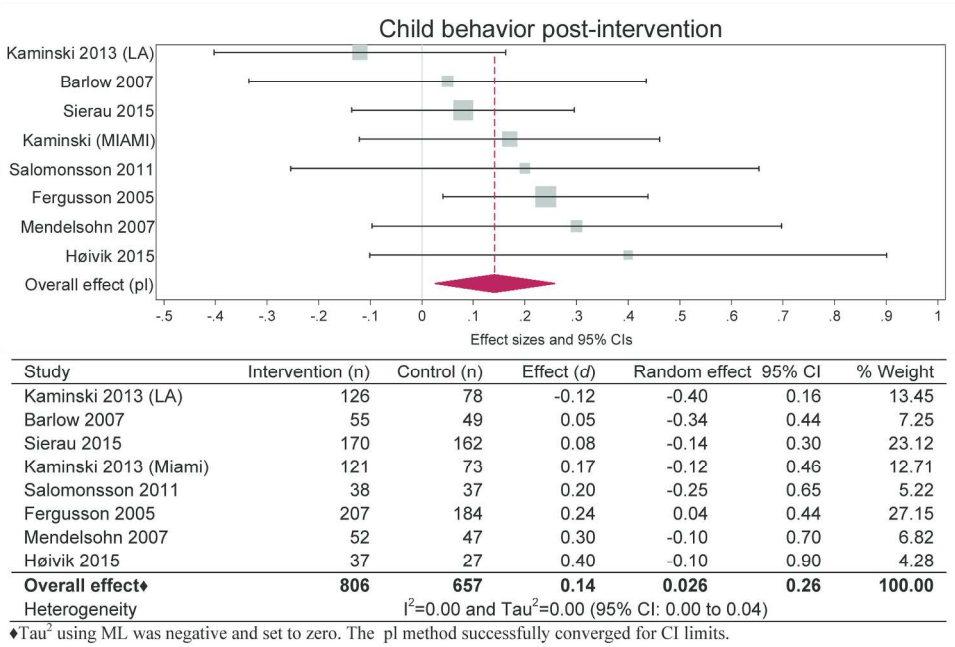


Figure 2 Meta-analysis of studies reporting child behavior outcomes at post-intervention

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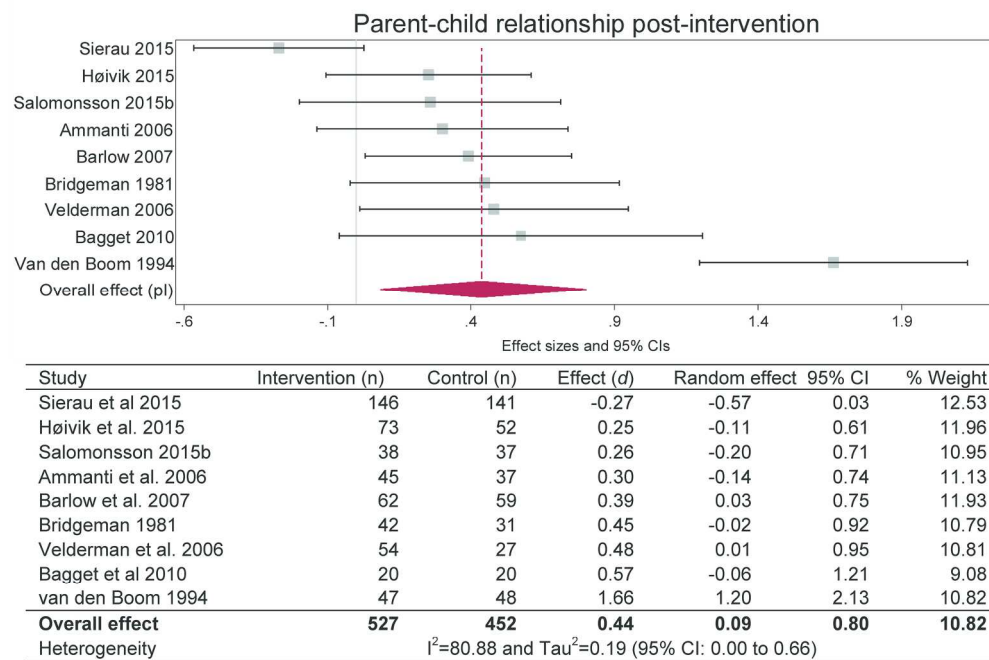


Figure 3 Meta-analysis of studies reporting parent-child relationship outcomes at post-intervention

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Online Table 1 Risk of Bias of included studies for child development and parent-child relationship outcomes

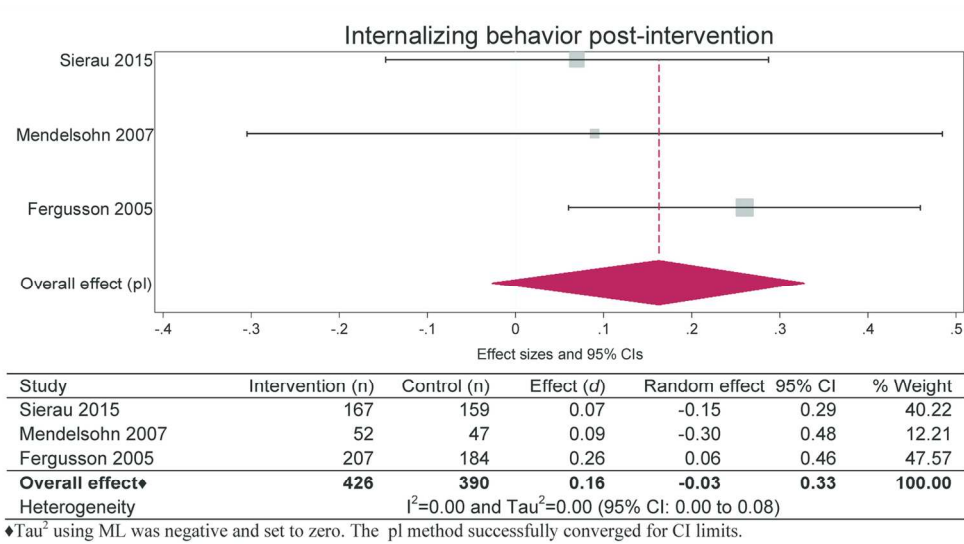
		Sequence generation	Allocation concealment	Blinding of outcome assessor	Incomplete outcome data	Free of selective reporting	A priori protocol	Free of other bias
	Outcome measures /Risk of bias domains							
Child development								
Barlow et al. 2006		L	L	-	-	-	U	-
	BITSEA/ Competence/Problems (Child behavior)	-	-	3	1	U	-	3
	BSID-II (Child cognitive and psychomotor development) BRS (Child behavior)	-	-	2	1	U	-	3
Bridgeman 1981		U	U	-	-	-	U	-
	Stanford-Binet (Child cognitive development) CFI (Child cognitive development) Pacific (Child cognitive development) Ammons (Child Communication/language development)	-	-	1	4	U	-	U
Kaminski et al. 2013*	DECA (Child behavior) SDQ (Child behavior)	L	L	3	3	1	Yes	1
Katz et al. 2011	BSID-II (Child cognitive and psychomotor development) BRS Bayley-II (Child behavior)	L	U	U	4	U	U	3
Mendelsohn et al. 2007		L	L	-	-	-	U	-
	BSID-II/MDI (Child cognitive development) PLS-3 (Child Communication/language development)	-	-	1	3	U	-	1
	CBCL/Internalizing/Externalizing/total (Child behavior)	-	-	3	3	U	-	1
Taylor et al. 1997	BSID II (Child cognitive and psychomotor development) CBCL (Child behavior)	L	U	1	3	U	U	1
		-	-	3	2	1	-	1
Fergusson et al. 2005	ITSEA/Externalizing/Internalizing/Total (Child behavior)	L	U	3	2	U	U	2
Fergusson et al. 2013		L	U	-	-	-	U	-
	SDQ (Child behavior - parent-rated)	-	-	3	2	U	-	2
	SDQ (Child behavior – teacher-rated)	-	-	2	2	U	-	2
Høivik et al. 2015	ASQ:SE (Child behavior)	H	H	3	4	1	Yes	U
Salomonsson et al 2011	ASQ:SE (Child behavior)	L	L	3	1	U	U	U
Salomonsson et al 2015a		L	L	-	-	-	U	-
	ASQ:SE (Child behavior) SDQ (Child behavior – parent-reported)	-	-	3	1	U	-	U
	SDQ (Child behavior – teacher-reported)	-	-	2	1	U	-	U
	CGAS (Child behavior)	-	-	1	1	U	-	U
Sierau et al. 2015		L	U	-	-	-	U	-
	BSID II/MDI/PDI (Child cognitive and psychomotor development) BRS Bayley-II (Child behavior) SETK-2 (Child Communication/language)	-	-	1	3	U	-	1
	ELFRA 1 and 2 (Child Communication/language) CBCL/Internalizing/Externalizing (Child behavior)	-	-	3	3	U	-	1

		Sequence generation	Allocation concealment	Blinding of outcome assessor	Incomplete outcome data addressed	Free of selective reporting	A priori protocol	Free of other bias
	Outcome measures /Risk of bias domains							
Parent-child relationship								
Ammaniti et al. 2006	Scales of Mother-Infant Interactional Systems (Parent-child relationship)	U	U	1	U	U	U	1
Bagget et al. 2010	Landry (Parent-child relationship)	U	U	1	1	U	U	1
Barlow et al. 2006	CARE-Index/ Maternal sensitivity/Infant cooperativeness (Parent-child relationship, maternal sensitivity)	L	L	2	1	U	U	3
Bridgeman 1981*	Mother-child relationship (based on Ainsworth) (Parent-child relationship)	U	U	1	4	U	U	U
Cassidy et al. 2013	SSP (Mother-Infant attachment)	U	U	1	1	U	Yes	1
Velderman et al 2006*	Maternal sensitivity (Ainsworth) (Maternal sensitivity) SSP (Mother-Infant attachment)	U	U	1	1	U	U	3
Taylor et al. 1997	NCATS (Parent-child relationship)	L	U	1	3	U	U	1
van den Boom 1994*	Maternal interactive behavior (Parent-child relationship) Infant interactive behavior (Parent-child relationship) SSP (Mother-Infant attachment)	U	U	1	U	U	U	1
van den Boom 1995*	SSP (Mother-Infant attachment) Mother-child interaction (based on Ainsworth)(Parent-child relationship, maternal sensitivity)	U	U	1	2	1	U	1
Høivik et al. 2015	EAS (Parent-child relationship)	H	H	1	2	1	Yes	U
Salomonsson et al 2015b		L	L	-	-	-	U	-
	SSAP (Mother-Infant attachment)	-	-	1	1	U	-	U
	EAS (Parent-child relationship)	-	-	1	U	U	-	2
Sierau et al. 2015	MBRS revised/Affectivity/Responsiveness (Parent-child relationship)	L	U	1	3	U	U	1

*Note: Risk of bias was conducted for each outcome. When risk of bias was the same for all included outcomes, only one score is provided in the table.

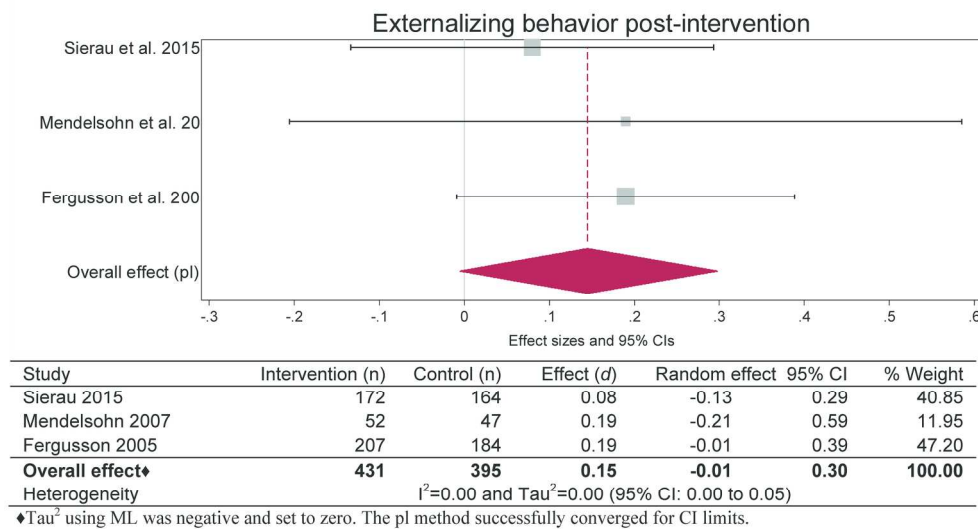
Note: In the 5-point scale 1 corresponds to low risk of bias and 5 correspond to high risk of bias. L= low risk of bias; H=high risk of bias; U= unclear risk of bias

Ammons: Ammons full range picture vocabulary test, ASQ:SE: Ages and Stages Questionnaires: Social Emotional, BITSEA: Brief Infant Toddler social and emotional assessment, BRS Bayley-II: Behavior Rating Scale, BSID-II: Bayley Scales of Infant Development, CBCL: Child Behavior Checklist, CFI: Concept Familiarity Index, CGAS: Children's Global Assessment Scale, DECA: The Devereux Early Childhood Assessment, EAS: Emotional availability scales, ELFRA 1 and 2: Elternfragebögen für die Früherkennung von Risikokindern, ITSEA: Infant Toddler social and emotional assessment, Landry: The Landry Parent-Child Interaction Scales, MBRS revised: Maternal behavior rating scale, NCATS: The nursing child assessment teaching scale, Pacific: Meyers Pacific Test Series, PLS-3: Preschool language scale-3, SDQ: Strengths and Difficulties Questionnaire, SETK-2: Sprachentwicklungstest für zweijährige Kinder, SSAP: Story Stem Assessment Profile, SSP: Strange situation procedure, Stanford-Binet: Stanford-Binet Intelligence Scales



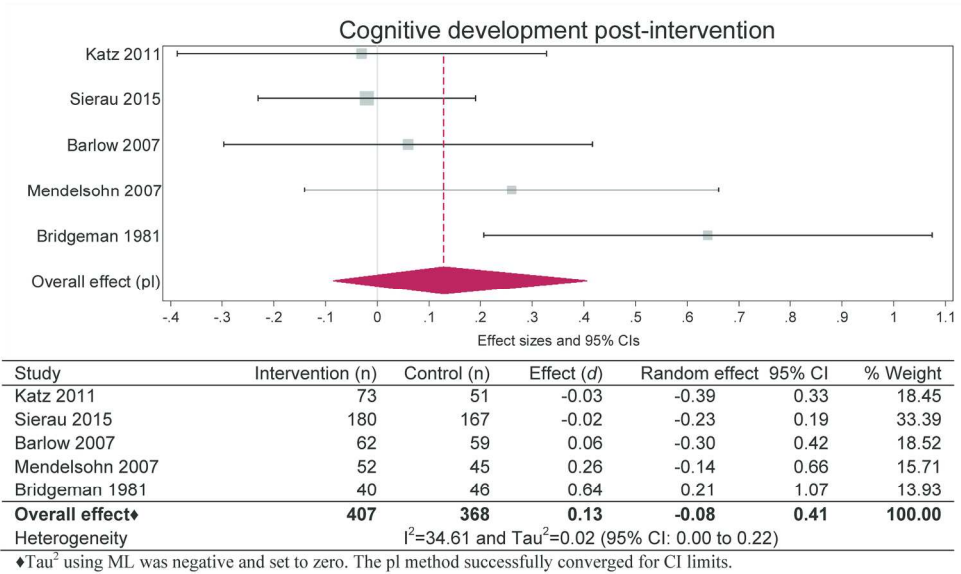
Online figure 1 Meta-analysis of studies reporting internalizing behavior at post-intervention

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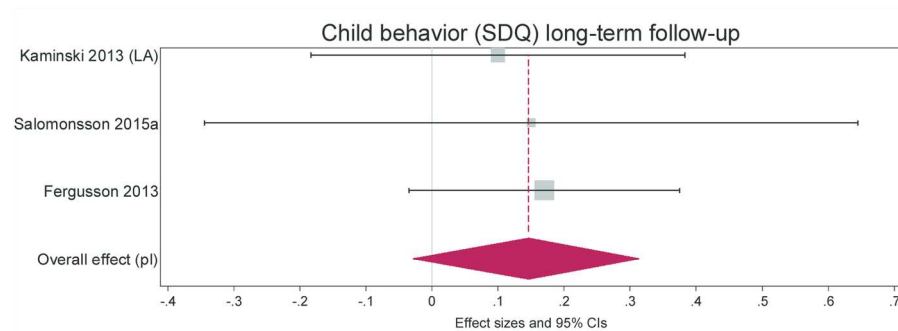
Online figure 2 Meta-analysis of studies reporting externalizing behavior at post-intervention

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Online figure 3 Meta-analysis of studies reporting cognitive development outcomes at post-intervention

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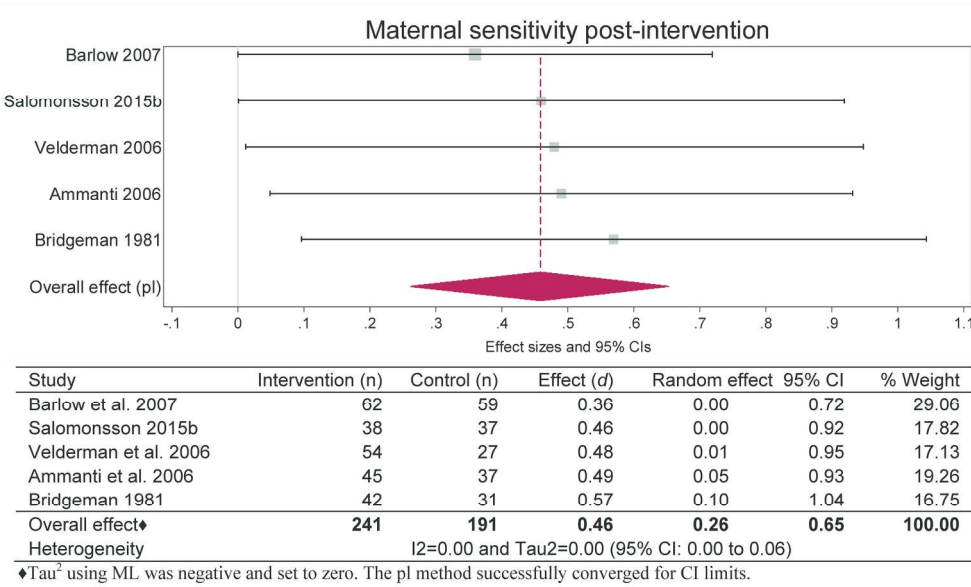


Study	Intervention (n)	Control (n)	Effect (d)	Random effect	95% CI	% Weight
Kaminski 2013 (LA)	124	78	0.10	-0.18	0.38	30.81
Salomonsson 2015a	32	31	0.15	-0.35	0.65	10.11
Fergusson 2013	199	171	0.17	-0.04	0.38	59.08
Overall effect*	355	280	0.15	-0.03	0.31	100.00
Heterogeneity	$I^2=0.00$ and $\text{Tau}^2=0.00$ (95% CI: 0.00 to 0.06)					

*Tau² using ML was negative and set to zero. The pl method successfully converged for CI limits.

Online figure 4 Meta-analysis of studies reporting child behavior outcomes at long-term follow up

76x43mm (600 x 600 DPI)



Online figure 5 Meta-analysis of studies reporting maternal sensitivity outcomes at post-intervention

92x56mm (600 x 600 DPI)

BMJ Open

The effects of parenting interventions for at-risk parents with infants: A systematic review and meta-analyses

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015707.R3
Article Type:	Research
Date Submitted by the Author:	17-Jul-2017
Complete List of Authors:	Rayce, Signe; VIVE – The Danish Centre of Applied Social Science Rasmussen, Ida ; VIVE – The Danish Centre of Applied Social Science Klest, Siyu; University of Tromsø, The Regional Centre for Child and Youth Mental Health and Child Welfare - North Patras, Joshua; University of Tromsø, The Regional Centre for Child and Youth Mental Health and Child Welfare - North Pontoppidan, Maiken; VIVE – The Danish Centre of Applied Social Science
Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	General practice / Family practice, Paediatrics, Public health
Keywords:	PAEDIATRICS, Community child health < PAEDIATRICS, PRIMARY CARE, Child & adolescent psychiatry < PSYCHIATRY, PUBLIC HEALTH, Clinical trials < THERAPEUTICS

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Manuscripts

The effects of parenting interventions for at-risk parents with infants: A systematic review and meta-analyses

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Word count: 4490

Keywords: Child development, infant development, parent-child relationship, parenting intervention, systematic review.

ABSTRACT

Objectives: Infancy is a critical stage of life, and a secure relationship with caring and responsive caregivers is crucial for healthy infant development. Early parenting interventions aim to support families in which infants are at risk of developmental harm. Our objective is to systematically review the effects of parenting interventions on child development and on parent–child relationship for at-risk families with infants aged 0–12 months.

Design: A systematic review and meta-analyses. We extracted publications from 10 databases in June 2013, January 2015, and June 2016, and supplemented with grey literature and hand search. We assessed risk of bias, calculated effect sizes, and conducted meta-analyses.

Inclusion criteria: 1) Randomized controlled trials of structured psychosocial interventions offered to at-risk families with infants aged 0–12 months in Western OECD countries, 2) Interventions with a minimum of three sessions and at least half of these delivered postnatally, and 3) Outcomes reported for child development or parent–child relationship.

Results: Sixteen studies were included. Meta-analyses were conducted on seven outcomes represented in 13 studies. Parenting interventions significantly improved child behavior ($d=0.14$; 95% CI: 0.03 to 0.26), parent–child relationship ($d=0.44$; 95% CI: 0.09 to 0.80), and maternal sensitivity ($d=0.46$; 95% CI: 0.26 to 0.65) post-intervention. There were no significant effects on cognitive development ($d=0.13$; 95% CI: -0.08 to 0.41), internalizing behavior ($d=0.16$; 95% CI: -0.03 to 0.33), or externalizing behavior ($d=0.16$; 95% CI: -0.01 to 0.30) post-intervention. At long-term follow-up we found no significant effect on child behavior ($d=0.15$; 95% CI: -0.03 to 0.31).

Conclusions: Interventions offered to at-risk families in the first year of the child's life appear to improve child behavior, parent–child relationship, and maternal sensitivity post-intervention, but not child cognitive development, internalizing, or externalizing behavior. Future studies should incorporate follow-up assessments to examine long-term effects of early interventions.

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Strengths and limitations of this study:

- Comprehensive search strategy and screening procedure
- Evaluation of child development and parent–child relationship outcomes
- Meta-analyses conducted on seven outcomes
- Few studies provide follow-up data
- Limited information on intervention implementation

For peer review only

INTRODUCTION

The first year of a child's life is characterized by rapid development that forms the foundation for lifelong developmental trajectories. A healthy environment is crucial for infants' emotional well-being and future physical and mental health.[1,2]

Experiencing severe adversity early in life can alter a child's development and lead to toxic stress responses, impairing brain chemistry and neuronal architecture.[3] For infants, severe adversity typically takes the form of caregiver neglect and physical or emotional abuse. The highest rates of child neglect and violent abuse occur for children younger than five,[4,5] with the most severe cases, which involve injury or death, occurring predominantly to children under the age of one.[6]

Mental health problems are common in infants, but symptoms are often less intrusive and less distinctly identifiable than for older children.[7–12] The Copenhagen Child Cohort study (CCC2000) found a prevalence rate of 18% for axis I diagnoses (according to DC: 0–3) in children aged 18 months, with regulatory disorders and disturbances in parent child–relationships being the most frequent mental health diagnoses.[8] The high prevalence in mental health diagnoses is important to note, as early onset of behavioral or emotional problems and adverse environmental factors increases the risk for negative outcomes later in life, such as substance abuse, delinquency, violence, teen pregnancy, school dropout, continued mental health problems, and long-term unemployment.[1,2,8,13–18]

Becoming a parent can be stressful and challenging,[19–21] particularly for parents who have experienced trauma, abuse, poverty, or other stressors.[22] Early-intervention parenting programs aim to assist parents with the challenges they experience. Most of these interventions teach caregivers specific strategies and skills

that foster healthy child development with an emphasis on promoting warm and responsive caregiving.[23]

Existing systematic reviews of the effects of parenting interventions offered to families with young children have shown mixed results.[14,24–29] In a review of 78 studies aimed at families with children aged 0–5 years, Piquero et al. found an average effect size (*g*) of 0.37 for decreased antisocial behavior and delinquency for intervention children.[14] Based on 22 studies, Barlow et al. concluded that there is tentative support for the effect of group-based interventions on emotional and behavioral adjustment in children aged 0–3 years.[28] Macbeth et al. found medium effect sizes for child or parent outcomes in a review of the Mellow Parenting intervention for families with children aged 0–8 years.[24] Barlow et al. found some evidence suggesting that parenting programs for teenage parents may improve parent–child interaction.[26] Barlow et al. reviewed parent–infant psychotherapy for high-risk families with infants aged 0–24 months; they found that infant attachment improved, but they found no effects on other outcomes.[27] Reviewing interventions offered to a universal group of parents of infants aged 0–1 year, Pontoppidan et al. found mixed and inconclusive results for child development and parent–child relationship outcomes.[25] Peacock et al. examined the effects of home visits for disadvantaged families with children aged 0–6 years and found improved child development outcomes when the intervention was implemented early.[30]

The existing reviews include very few studies of interventions for at-risk parents that are initiated within the first year of the infants’ life. Therefore, we do not know if early preventive parenting interventions are effective in improving child development or parent–child relationship outcomes. The aim of this review was to

systematically review the effects of parenting interventions offered to at-risk families with infants aged 0–12 months. We included randomized controlled trials of parenting interventions reporting child development or parent–child relationship outcomes at post-intervention or follow-up.

METHODS

Search strategy

This review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We did not register a protocol. The database searches were performed in June 2013 and were updated in January 2015 and June 2016. We searched ten international bibliographic databases: Campbell Library, Cochrane Library, CRD (Centre for Reviews and Dissemination), ERIC, PsycINFO, PubMed, Science Citation Index Expanded, Social Care Online, Social Science Citation Index, and SocIndex. Operational definitions were determined for each database separately. The main search was made up of combinations of the following terms: infant*, neonat*, parent*, mother*, father*, child*, relation*, attach*, behavi*, psychotherap*, therap*, intervention*, train*, interaction, parenting, learning, and education. The searches included Medical Subject Headings (MeSH), Boolean operators, and filters. Publication year was not a restriction. Furthermore, we searched for grey literature, hand searched four journals, and snowballed for relevant references.

Eligibility criteria and study selection

We screened all publications based on title and abstract. Publications that could not be excluded were screened based on the full-text version. Table 1 shows the inclusion and exclusion criteria.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Population	
At-risk population of parents of infants 0-12 months old in western OECD countries	Studies including specific groups such as young mothers (mean age <20 years), divorced parents, parents with mental health problems such as schizophrenia and abuse and children born pre-term, at low birth weight or with congenital diseases.
Intervention	
Structured psychosocial parenting intervention consisting of at least three sessions and initiated either antenatal or during the child's first year of life with at least half of the sessions delivered postnatally.	Interventions not focusing specifically on parenting (e.g. baby massage, reading sessions with child, or breastfeeding interventions), and unstructured interventions (e.g. home visits not offered in a structured format).
Control group	
No restrictions were imposed. All services or comparison interventions received or provided to the control group were allowed.	
Outcome	
Child development and/or parent-child relationship outcomes	Studies reporting only physical development or health outcomes such as height, weight, duration of breastfeeding, and hospitalization. Papers with insufficient quantitative outcome data to generate standardized mean differences (Cohen's d), odds ratios (OR) and confidence intervals (CI).
Design	
Randomized controlled trials (RCT) or quasi-RCTs.	Other study designs such as case control, cohort, cross sectional, and systematic reviews
Publication type	
Studies presented in peer-reviewed journals, dissertations, books or scientific reports.	Abstracts or conference papers. Studies published in languages others than English, German or the Scandinavian languages (Danish, Swedish and Norwegian).

We excluded studies that examined parenting interventions aimed at specific risk groups such as teen mothers; parents with severe mental health problems; or parents with children born pre-term, at low birth weight, or with congenital diseases. Families experiencing difficulties such as these have specific needs, and interventions aimed at these groups may be more targeted when compared to parenting interventions aimed at broader, at-risk groups of parents. Since our focus

was parenting interventions aimed at at-risk parents in general, we excluded studies developed for specific risk-groups.

Each publication was screened by two research assistants under close supervision by MP and SBR. Uncertainties regarding inclusion were discussed with MP and SBR. Screening was performed in Eppi-Reviewer 4.[31]

Data extraction and risk of bias assessment

We developed a data extraction tool for the descriptive coding and extracted information on 1) study design, 2) sample characteristics, 3) setting, 4) intervention details, 5) outcome measures, and 6) child age at post-intervention and at follow-up. Information was extracted by one research assistant and subsequently checked by another reviewer. Disagreements were discussed with MP or SBR. Primary outcomes were child behavior and the parent–child relationship. Secondary outcomes were other child development markers such as cognitive development, language/communication, psychomotor development, parent sensitivity, and attachment classification. When reported, both total scores and subscale scores were extracted.

Numeric coding of outcome data was conducted by ISR and checked by MP or SBR. We resolved disagreements by consulting a third reviewer. Risk of bias was assessed separately for each relevant outcome for all studies based on a risk-of-bias model developed by Professor Barnaby Reeves and the Cochrane Nonrandomized Studies

Method Group (Reeves, Deeks, Higgins, & Wells, unpublished data, 2011). This extended model is organized and follows the same steps as the existing risk-of-bias model presented in the Cochrane Handbook, chapter 8.[32] The assessment was conducted by ISR and SBR. Any doubts were discussed with a third reviewer.

Analyses

We calculated effect sizes for all relevant outcomes for which sufficient data was provided. Effect sizes were reported using standardized mean differences (Cohen’s *d*) with 95% confidence intervals for continuous outcomes. Data included post-intervention and follow-up means, raw standard deviations, and sample size. Alternatively, *t*-values, *F*-tests, χ^2 , *p*-values, mean differences, eta-square and β -coefficients were used. For dichotomous outcomes, we used odds ratios (ORs) with 95% confidence intervals as the effect size metric when presenting the effects of the individual studies. When used in meta-analyses, ORs were converted to *d* using the method presented in Chin (2000).[33] The data used to calculate ORs were number of events and sample sizes. We contacted the corresponding author for more information if a paper presented insufficient information regarding numeric outcomes. When available, we used data from adjusted analyses to calculate effect sizes. When using the adjusted mean difference, we used the unadjusted standard deviations in order to be able to compare the effect sizes calculated from unadjusted and adjusted means, respectively. To calculate effect sizes, we used the Practical Meta-Analysis Effect Size Calculator developed by David B. Wilson at George Mason University and provided by the Campbell Collaboration.[34]

Meta-analysis was performed when the intervention outcome and the time of assessment were comparable. If a single study provided more than one relevant measure or only subscales for a given meta-analysis, then the effect sizes of the respective measures were pooled into a combined measure.

Random effects inverse variance weighted mean effect sizes were applied and 95% confidence intervals were reported. Studies with larger sample sizes were therefore given more weight, all else being equal. Due to the relatively small number of studies and an assumption of between-study heterogeneity, we chose a random-effects model using the profile-likelihood estimator as suggested in Cornell 2014.[35] Variation in standardized mean difference that was attributable to heterogeneity was assessed with the I^2 . The estimated variance of the true effect sizes was assessed by the Tau^2 statistic. When indication of high heterogeneity ($I^2 > 75\%$) was found, sensitivity analyses were conducted, removing one study at a time in order to identify a potential source of heterogeneity. The small number of studies in the respective meta-analyses did not allow for subgroup analyses. Results were summarized for child development (behavior, cognitive development, psychomotor development, and communication/language) and parent-child relationship (relationship, sensitivity, and attachment classification) outcomes for the following assessment times: post-intervention (PI- immediately after intervention ending), short-term (ST - less than 6 months after intervention ending), medium-term (MT - 7–12 months after intervention ending), and long-term (LT - more than 12 months after intervention ending) follow-up.

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RESULTS

Description of studies

The literature search identified 17,984 articles after the removal of duplicates. A flow diagram for the process of study inclusion is illustrated in figure 1. Nineteen papers representing 16 individual studies were included. Kaminski et al. 2013 represented two trials (LA & Miami) and is handled as two studies when reporting results.[36] Four studies were excluded, as they provided insufficient numeric data to calculate effects sizes and CIs.[37–40] One study was excluded due to unacceptably high risk of bias.[41]

Figure 1 about here

Included studies

Except for one study,[42] which compared a group-based intervention to an individual-based intervention, all studies compared interventions to a no-intervention control or to treatment as usual (TAU) . A few studies offered minor interventions such as psychoeducation and social worker contact to the control group.[43–46] Eight studies were American,[36,42–44,46–48]two were conducted in the Netherlands,[49–51] and one study each was from Sweden,[52–54] Germany,[55] Italy,[56] New Zealand,[57,58] Norway,[45] and the United Kingdom.[59] The oldest study was published in 1981[47] and the most recent studies were published in 2015.[45,53–55] Sample size ranged from 40 participants [43] to 755.[55]

Participant characteristics

Table 2 shows study participant characteristics. All families exhibited at least one risk factor such as poverty, low education, or living in deprived areas. Some samples were further characterized by, for example, insecure attachment, risk of developmental delay, or having a difficult or irritable infant. We did not include studies targeting families with more severe problems such as drug abuse, incarceration, or chronic diseases.

Mothers' mean age ranged from 21–33 years. Four studies recruited primiparous mothers,[44,49–51,55] five studies also included mothers with more than one child, [43,45,46,48,52–54] and seven studies did not report parity.[36,42,47,56–59]

Table 2 Participant characteristics

Study	Country	Risk	Mother mean age at start in years	Child age at start in months	Primiparous %	Intervention, n	Control, n
Ammaniti et al[56]	Italy	Depressive or psychosocial risk	33	Third trimester	Not reported	47	44
Baggett et al[43]	USA	Low income	Intervention: 25; Control: 27	~4	Mean number of children: 1.75	20	20
Barlow et al[59]	UK	Vulnerable	< 17 years: Intervention:17.9%; Control:22.2 %	Second trimester	Not reported	68	63
Bridgeman et al[47]	USA	Low income	17 – 35	2	Not reported		Unclear ‡
Cassidy et al[44]	USA	NBAS or low income	24	6.5-9	100	85	84
Fergusson et al[57] & Fergusson et al[58]	New Zealand	Two or more risk factors present	Mother: Intervention: 24; Control: 24 Father: Intervention: 27; Control: 27	Not reported (Recruited within 3 months of birth)	Not reported	206	221
Hoivik et al[45]	Norway	Interactional problems	30	7.3	72	88	70
Kaminski et al[36]	USA	Low income	24	Prenatally (LA), at birth (Miami)	Not reported	338	236
Katz et al[46]	USA	African American with inadequate prenatal care	25	0	Mean number of children: 2.9	146	140
Mendelsohn et al[48]	USA	Low educated latina mothers	Intervention: 30; Control: 30	0.5	Intervention: 21.2; control: 36.2	77	73
Salomonsson et al[52]Salomonsson et al[53] & Salomonsson et al[54]	Sweden	Worried mothers	Intervention: ~34; Control: ~32	Intervention:4.4; Control:5.9	Intervention:81; Control:78	40	40
Sierau et al[55]	Germany	Economic- and social risk factors	Intervention: 21; Control: 22	Third trimester	100	394	361
Taylor et al[42]	USA	Poverty, single marital status, low education, age <20, previous substance abuse, or a history of abuse	Intervention (n): <20: 44, 20-30:122, >30:34; Control: <20:58, 20-30:108, >30:34	3	Not reported	50	50
van den Boom et al[49] & van den Boom et al[50]	Netherlands	Lower-class mothers with irritable infants	Mother: 25 Father: Intervention:28; control:29	6	100	50	50
Velderman et al [51]	Netherlands	Insecure attachment	28	~7	100	54	27

‡ The study only reported number of participants in each analysis

Interventions

Table 3 presents the intervention details. Eight studies offered individual home visits,[44–46,49–51,55–59] three studies offered individual sessions (outside the home),[47,48,52–54] one study offered group sessions,[42] one study offered web-coaching,[43] two studies combined individual sessions and group sessions,[36] and one study combined home visits and group sessions.[46] Intervention was initiated prenatally in four studies,[36,55,56,59] and 12 studies initiated intervention after the child was born.[36,42–54,57,58] The duration of the interventions varied from relatively short interventions (≤ 6 months) [43,44,49–54] to medium-length interventions (7–12 months) [42,45,46,56,59] to long interventions (≥ 24 months).[36,47,48,55,57,58]

Table 3 Intervention characteristics

Study	Name of intervention	N	Intervention				Control	Outcome	
			Begins	Intensity	Format	Ends/duration		Measure	Child age
Ammaniti et al.[56]	Home Visiting Program (HV)	91	8 months pregnant	Weekly and every second week. ~ 36 sessions	Home visits	Ends: 12 months of age	No intervention	Parent-child relationship	12 months
Baggett et al.[43]	Infant Net	40	3-8 months of age	10 online sessions + 1 read to me session + weekly coach calls	Web-coaching	Duration: 6 months	TAU+provided computer and internet technology	Parent-child relationship	~10 months
Barlow et al.[59]	Intervention based on The Family Partnership Model	131	6 months antenatal	Weekly (mean sessions 41.2)	Home visits	Duration: 18 months	TAU	Parent-child relationship Child development	12 months
Bridgeman et al.[47]	Parent Child Development Center (PCDC)	Uncl ear†	2 months of age	Twice a week for a total of six hours	Individual sessions	Ends: 36 months of age	No intervention	Parent-child relationship Child developmentΔ	36 months
Cassidy et al.[44]	Circle of security, home visiting	174	6.5-9 months of age	1 hour every 3 weeks	Home visits	Duration: 3 months	Psychoeducational sessions (3*1 hour)	Parent-child relationshipΔ	12 months
Fergusson et al.[57] & Fergusson et al.[58]	Early Start (2 levels of intensity)	443	Recruited within 3 months of birth	Varied. Low level: up to 2.5 hours per 3 months	Home visits	Duration 36 months	No intervention	Child development	~36 months ~9 years
Høivik et al.[45]	Video feedback, Marte Meo	158	Varies, between 0-24 months of age ~7.3 months of age	8 sessions, 9-13 months (mean 11.5 months)	Home visits	Duration: 9-13 months	TAU + health center nurses if needed	Parent-child relationship Child development	~9-10 months ~15-16 months
Kaminski et al., Los Angeles[36]	Legacy for Children	574	Prenatal in LA	Weekly (2.5 hour) for 3 years in LA	Group sessions and individual sessions	Duration: 3 years in LA	No intervention	Child development	~36 months ~48 months ~60 months
Kaminski et al., Miami [36]	Legacy for Children		At birth in Miami	Weekly (1.5 hour) for 5 years in Miami	Group sessions and individual sessions	Ends: 5 years of age in Miami	No intervention	Child development	~60 months
Katz et al.[46]	Pride in Parenting	286	At birth	Weekly from birth through 4 month and biweekly from 5 to 12	Home visits+groups	Ends: 12 months of age	TAU+monthly contacts from	Child development	12 months

Study	Name of intervention	N	Intervention				Control	Outcome	
			Begins	Intensity	Format	Ends/duration		Measure	Child age
	Program (PIP)			months	sessions		a hospital-based social worker		
Mendelsohn et al.[48]	Video Interaction Project (VIP)	150	2 weeks postpartum	12 sessions (30-45 min. each)	Individual sessions	Ends: 36 months of age	TAU	Child development	33 months
Salomonsson et al.[52], Salomonsson et al[53] & Salomonsson et al[54]	Psychoanalytic treatment	80	Varied: Infants below 1½ years, mean age <6 months	23 session (median), 2-3 hour pr. week	Individual sessions	Duration: Unclear, assumingly 6 months	TAU	Parent-child relationship Child development	4½ years ~11 months ~54 months
Sierau et al[55]	Pro Kind	755	36 gestational weeks (assumingly)	Weekly (first 4 weeks after program intake and 4 weeks after birth), bi-weekly, and monthly (last half year of treatment)	Home visits	Ends: 24 months old (assumingly)	TAU	Parent-child relationship Child development	24 months
Taylor et al[42]	Group well child care (GWCC)	220	3 months of age	7 sessions (45-60 min.) up to 15 months	Group sessions	Ends: ~15 months of age	Individual well child care (IWCC)†	Parent-child relationshipΔ Child developmentΔ	~ 15 months
van den Boom et al[49] & van den Boom et al[50]	-	100	6 months of age (baseline 10 days after birth)	1 sessions (2 hours) every 3 weeks for 3 months	Home visits	Ends: 9 months of child's age	No intervention	Parent-child relationship	9 months 12 months 18 months
Velderman et al[51]	1. VIPP 2. VIPP-R	81	~ 7 months of age	4 visits (1.5-3 hours) over 9-12 weeks	Home visits	Duration: 9 to 12 weeks	No intervention	Parent-child relationship	11-13 months 13 months

TAU: Treatment as Usual

◇ Not a standardized test

† Two active intervention groups, **no** control group

Δ Outcome(s) not included in meta-analysis

* Study only reported number of participants in each analysis

Outcomes

Child development and the parent–child relationship were measured based on parent-report questionnaires, teacher-report questionnaires, structured interviews, and videos. Five studies reported only child development outcomes,[36,46,48,57,58] five reported only parent–child relationship outcomes,[43,44,49–51,56] and six reported both.[42,45,47,52–55,59] Timing of assessment was divided into four assessment times: (1) post-intervention follow-up, (2) short-term follow-up, (3) medium-term follow-up, and (4) long-term follow-up.

All studies reported a post-intervention outcome. Two studies reported an outcome at short-term follow-up,[45,49,50] two at medium-term follow-up,[36,49] and three at long-term follow-up.[36,52–54,57,58]

Risk of Bias

The risk of bias assessments are shown in the online table 1 and are divided into child development outcomes and parent-child relationship outcomes. Many studies provided insufficient information for at least two domains, thereby hindering a clear judgment for risk of bias. Risk of bias generally ranged between low and medium. However, three studies had outcomes where one or two domains had a moderate risk of bias.[45–47] Two studies had outcomes with high risk of bias in one domain.[45,47] Based on an overall judgement across risk-of-bias domains, two outcomes (CTBS math and BTBS reading scores) [47] and one study [41] were excluded from the review. The reasons were, on the one hand, high risk of bias in relation to “incomplete data addressed” combined with unclear risk of bias judgements in all other domains,[47] and, on the other hand, the pronounced baseline imbalance not being addressed.[41]

1 The outcomes included in the child development meta-analyses were characterized
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3 by low to medium and unclear risk of bias domains, whereas the meta-analyses on
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5 parent–child relationship outcomes primarily included outcomes with a relatively
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7 low or unclear risk of bias. Two studies represented in the meta-analyses of both
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9 child development and parent–child relationship outcomes had domains assessed as
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11 having moderate or high risk of bias.[45,47]
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14 **Child development outcomes at post-intervention**

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16 Table 4 presents the study outcomes for the individual studies.
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Table 4 Child development outcomes as reported across studies included in the systematic review

Study	Measure	Assess ment	Child age in month s	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
PI	Behavior										
Barlow et al. 2007[59]	Total problem score BITSEA ◯	Q	12	55	33.52	38.81	49	35.55	39.63	0.05(-0.33;0.44)	
	Competence BITSEA	Q	12	53	14.06	3.65	43	13.37	3.53	0.19(-0.21;0.60)	
	BRS	O	12	62	38.37	5.71	59	38.69	5.5	-0.06(-0.41;0.30)	
Høivik et al. 2015[45]	Total score ASQ:SE	Q	~9-10	37			27			0.40(-0.10;0.90)	β=-7.22, SD of DV=18.51 ■
Salomonsson et al. 2011[52]	Total score ASQ:SE ◯	Q	~11	38	1.00	0.72	37	1.14	0.70	0.20(-0.26;0.65)	Becker's δ=0.25(adjusted for baseline ASQ:SE)
Sierau et al. 2015[55]	Internalizing CBCL ◯	Q	24	167	9.51	5.95	159	9.94	5.65	0.07(-0.14;0.29)	
	Externalizing CBCL ◯	Q	24	172	15.93	7.56	164	15.34	7.23	0.08(-0.13;0.29)	
	BRS	O	24	160	53.10	26.74	142	57.13	27.79	-0.15(-0.37;0.08)	
Fergusson et al. 2005[57]	Externalizing ITSEA (short)	Q	~36	207			184			0.19 (-0.01;0.39)	Cohen's d provided in paper
	Internalizing ITSEA (short)	Q	~36	207			184			0.26(0.06;0.47)	Cohen's d provided in paper
	Total problem score ITSEA(50 item)	Q	~36	207			184			0.24(0.04;0.44)	Cohen's d provided in paper
Kaminski et al. 2013, LA[36]	DECA Behavioral concerns	Q	36	126			78			-0.12(-.48;0.25) ✕	OR=0.81 (0.42;1.56)
	DECA Socioemotional problems	Q	36	127			79			-0.04(-0.49;0.43) ✕	OR=0.93(0.41;2.17)
Kaminski et al. 2013, Miami[36]	DECA Behavioral concerns	Q	60	121			73			0.32(-0.07;0.7) ✕	OR=1.78(0.88;3.57)
	DECA Socioemotional problems	Q	60	122			73			0.00(-0.48;0.49) ✕	OR=1.00(0.42;2.44)
	SDQ Conduct problems	Q	60	122			73			0.18(-0.14;0.52) ✕	OR=1.39(0.77; 2.56)
	SDQ Hyperactivity _i	Q	60	121			73			0.31(-0.21;0.84) ✕	OR=1.75(0.69;4.55)
	SDQ Peer problems	Q	60	121			73			-0.14(-.52;0.24) ✕	OR=0.78(0.39;1.54)
Mendelsohn et al. 2007[48]	Total problem score CBCL◯	Q	33	52	50.2	10.0	47	53.2	9.7	0.30(-0.09; 0.70)	
	Externalizing CBCL◯	Q	33	52	50.0	9.8	47	51.8	9.4	0.19(-0.21;0.58)	
	Internalizing CBCL◯	Q	33	52	52.9	9.9	47	53.8	9.3	0.09(-0.30;0.49)	
Katz et al. 2011[46]	BRS	O	12	73			51			0.83(-0.43;2.09) ✕	Normal/non-optimal: Intervention:72/1, control: 48/3, OR=4.5 (0.45; 44.55)
PI	Cognitive development										
Barlow et al. 2007[59]	MDI	O	12	62	93.74	10.98	59	93.03	10.89	0.06(-0.29;0.42)	
Katz et al. 2011 [46]	MDI	O	12	73	101.0	12.4	51	101.4	17.3	-0.03(-0.39;0.33)	
Taylor et al. 1997[42]	MDI	O	~15	50	99.3	14.8	50	100.4	14.3	-0.08(-0.47;0.32) ▲	
Sierau et al. 2015[55]	MDI	O	24	180	87.37	14.74	167	87.64	14.74	-0.02(-0.23;0.19)	
Bridgeman et al. 1981, New Orleans, Louisiana[47]	Intelligence Stanford-Binet	O	36	46	104.22	10.36	52	96.69	12.20	0.66(0.25;1.07)	R=0.49 (incl.all independent variables)
	Concept attainment CFI	O	36	38	33.39	4.69	43	28.02	7.01	0.89(0.43;1.35)	
	Perception Pacific test series	O	36	32	32.09	5.29	42	30.00	6.86	0.34(-0.13;0.80)	
Mendelsohn et al. 2007[48]	MDI	O	33	52	86.1	7.5	45	83.9	9.7	0.26(-0.14;0.66)	

Study	Measure	Assessment	Child age in months	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
PI	Psychomotor development										
Katz et al. 2011[46]	PDI	O	12	73	95.1	13.6	51	93.1	11.9	0.15(-0.20;0.51)	
Taylor et al. 1997[42]	PDI	O	~15	50	103.6	11.5	50	100	12.4	0.30(-0.09;0.70) ▲	
Sierau et al. 2015[55]	PDI	O	24	180	92.86	15.08	167	92.81	14.10	0.00(-0.21;0.21)	
PI	Communication/language										
Bridgeman et al. 1981, New Orleans, Louisiana[47]	Ammons	O	36	34	13.44	3.38	38	11.11	3.09	0.72(0.24;1.20)	
Mendelsohn et al. 2007[48]	PLS-3	O	33	52	80.7	10.2	45	81.1	10.6	-0.04(-0.44;0.36)	
Sierau et al. 2015[55]	ELFRA	O	24	169	102.64	64.69	161	107.84	66.63	-0.08(-0.30;0.14)	
	SETK-2	O	24	141	0.78	0.58	128	0.80	0.61	-0.03(-0.27;0.21)	
SF	Behavior										
Høivik et al. 2015[45]	ASQ:SE	Q	~15-16	26			27			1.05(0.47;1.62)	β=-13.79, SD of DV=15.02 ■
MF	Behavior										
Kaminski et al. 2013 LA[36]	DECA Behavioral concerns	Q	48	124			78			0.26(-0.14;0.66) X	OR=1.61(0.78;333)
	DECA Socioemotional problems	Q	48	124			78			0.00(-0.55;0.55) X	OR=1.00(0.37; 2.70)
	SDQ Conduct problems	Q	48	124			78			0.18(-0.14;0.51) X	OR=1.39 (0.77;2.5)
	SDQ Hyperactivity _i	Q	48	124			78			-0.37(-0.01;0.26) X	OR=0.51(0.16;1.61)
	SDQ Peer problems	Q	48	124			78			-0.12(-0.49;0.26) X	OR=0.81 (0.41;1.61)
LF	Behavior										
Fergusson et al. 2013[58]	SDQ ○	Q	~108	199	9.91	0.91	171	10.08	1.06	0.17(-0.03; 0.38)	
Kaminski et al. 2013 LA[36]	DECA Behavioral concerns	Q	60	116			71			0.27(-0.21;0.72) X	OR=1.62 (0.69;3.70)
	DECA Socioemotional problems	Q	60	117			73			0.49(0.05;1.01) X	OR=2.44 (1.10;6.25)
	SDQ Conduct problems	Q	60	116			71			-0.03(-0.39;0.33) X	OR=0.94 (0.49;1.82)
	SDQ Hyperactivity _i	Q	60	116			71			0.17(-0.37;0.7) X	OR=1.35(0.51;3.57)
	SDQ Peer problems	Q	60	116			71			0.17(-0.24;0.58) X	OR=1.37(0.65;2.86)
Salomonsson et al 2015a[53]	ASQ:SE	Q	54	32	0.98	0.90	32	0.88	0.68	0.13(-0.37; 0.62)	
	SDQ	Q _{parent}	54	32	8.17	5.54	31	7.39	5.19	0.15(-0.35;0.64)	
	SDQ	Q _{teacher}	54	24	5.71	4.32	27	6.59	5.31	-0.18(-0.73; 0.37)	
	CGAS Functioning	Q	54	31	78.39	12.8	30	68.87	14.74	0.69(0.17; 1.21)	

X Calculation based on dichotomous outcome

○ Reverse scoring – high score is negative

■ Adjusted for ASQ baseline score

▲ No control group. Two interventions were compared.

U, unadjusted; Q, questionnaire; O, observation; PI, post-intervention; SF, short-term follow-up (≤6 months post intervention); MF, mid-term follow-up (7-12 months); LF, long-term follow-up (>12 months post-intervention); BITSEA, Brief Infant Toddler Social Emotional Assessment; ASQ:SE, Ages & Stages Questionnaires: Social-Emotional; CBCL, Child Behavior Checklist; ITSEA, Infant Toddler Social Emotional Assessment; DECA, Devereux Early Childhood Assessment; MDI, Mental Developmental Index; PDI, Psychomotor Development Index; CFI, Concept Familiarity Index; PLS-3, Preschool Language Scale; SDQ, Strengths and Difficulties Questionnaires; CGAS, Children's Global Assessment Scale

Meta-analysis of the primary outcome is reported in figure 2, secondary outcomes in online figures.

Figure 2 about here

Behavior

The meta-analysis of parent-reported child behavior shown in figure 2 included eight studies.[36,45,48,52,55,58,59] The analysis showed a small but significant effect on child behavior ($d=0.14$; 95% CI: 0.03 to 0.26) favoring the intervention group. One study that offered a considerably longer intervention than the rest was removed for a sensitivity analysis, which found that the results were not substantially affected by removing the study.[36] The study was therefore kept in the analysis. For the internalizing and externalizing subscales, no significant difference between intervention and control group was found (see online figure 1 and 2). None of the behavioral outcomes that were not included in a meta-analysis showed statistically significant differences between intervention and control group.[46,55,59]

Three studies reported observer-rated child behavior using the behavioral rating scale (BRS) from Bayley II.[46,55,59] One study used a dichotomized version of BRS,[46] which may not have been able to detect changes in this population since all but one (intervention) and three (control) children were rated as unproblematic. Meta-analysis was therefore not conducted. None of the studies found statistically significant effects.

Cognitive development

The meta-analysis on cognitive development included five studies (online figure 3).[46–48,55,60] There was no significant difference between intervention and control groups ($d=0.13$; 95% CI: -0.08 to 0.41). A sensitivity analysis was conducted in which the one study that did not apply the MDI was removed, [47] and the analysis found that the effect size decreased ($d=0.03$) but remained insignificant (95% CI: -0.12 to 0.21).

Psychomotor development

We could not perform meta-analysis for psychomotor development outcomes, as one study provided data comparing two active interventions.[42] Of the three studies that included psychomotor development, none of them found significant effects.[42,46,55]

Communication/language development

We could not perform meta-analysis for communication/language outcomes, as the measures varied considerably. Two studies found no significant effect on communication/language development,[48,55] whereas one found significantly improved communication/language development for the intervention group ($d=0.72$; 95% CI: 0.24 to 1.20).[47]

Child development outcomes at follow-up

Because few studies reported child development outcomes at follow-up, we were only able to conduct a meta-analysis for one of the follow-up outcomes.

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The meta-analysis of parent-rated child behavior at long-term follow-up, as shown in online figure 4, included child behavior scores (SDQ) from three studies.[36,53,58] No significant effect was found ($d=0.15$; 95% CI: -0.03 to 0.31).

At short-term follow-up, one study found a significant positive effect on child behavior ($d=1.05$; 95% CI: 0.47 to 1.62).[45] At medium-term follow-up, one study found no significant effects on behavioral concerns, conduct problems, hyperactivity, or peer problems.[36] At long-term follow-up, one study found a significant positive effect on child functioning (CGAS) ($d=0.69$; 95% CI: 0.17 to 1.21),[53] and one study found a significant positive effect on child socio-emotional development (DECA) (OR=2.44; 95% CI: 1.10 to 6.25).[36]

No studies reported follow-up data on cognitive development, communication/language, or psychomotor development.

Parent–child relationship at post-intervention

Table 5 presents the study outcomes for the individual studies.

Table 5 Parent-child relationship outcomes as reported across studies included in the systematic review

Study	Measure	Assessment	Child age (months)	Intervention			Control			Cohen's d	Other statistics
				n	Mean	SD	n	Mean	SD		
Ammaniti et al. 2006[56]	Sensitivity (M) SMIIS	V	12	45	7.25	1.06	37	6.67	1.31	0.49(0.05;0.93)	
	Cooperation (D) SMIIS	V	12	45	8.11	0.94	37	7.67	1.19	0.42(-0.02;0.85)	
	Interference (M) SMIIS ○	V	12	45	1.36	0.81	37	1.52	0.80	0.20(-0.24;0.63)	
	Affective state (M) SMIIS ○	V	12	45	1.15	0.44	37	1.39	0.66	0.44(-0.00;0.88)	
	Self-regulative behaviors (C) SMIIS	V	12	45	1.92	0.95	37	1.96	0.99	-0.04(-0.48;0.39)	
Baggett et al. 2010[43]	Positive behaviors (C) Landry	V	~10	20			20			0.69(0.05;1.33)	Eta ² =0.107
	Positive behaviors (P) Landry	V	~10	20			20			0.45(-0.17;1.08)	Eta ² =0.049
Barlow et al. 2007[59]	Sensitivity (M) CARE-index	V	12	62	9.27	2.67	59	8.2	3.26	0.36(0.00; 0.72)	
	Cooperativeness (C) CARE-index	V	12	62	9.35	3.08	59	7.92	3.7	0.42(0.06;0.78)	
Bridgeman et al. 1981, New Orleans, Louisiana[47]	Positive Language (M) (In-house)	V	36	42	30.26	27.07	31	7.24	39.93	0.70(0.22;1.17)	
	Sensitivity (M) Ainsworth's rating scale	V	36	42	6.29	1.62	31	5.19	2.30	0.57(0.09;1.04)	
	Acceptance (M) Ainsworth's rating scale	V	36	42	6.87	1.31	31	6.52	1.55	0.25(-0.22;0.71)	
	Cooperation (M) Ainsworth's rating scale	V	36	42	6.03	1.96	31	5.48	1.98	0.28(-0.19;0.75)	
Høivik et al. 2015[45]	EAS ○	V	~9-10	73	151.90	19.6	52	145.84	29.24	0.25(-0.11;0.61)	
Salomonsson et al 2015b[54]	Sensitivity (M) EAS	V	~11	38	0.64	0.13	37	0.57	0.17	0.46(0.00;0.92)	
	Structuring (M) EAS	V	~11	38	0.71	0.12	37	0.68	0.16	0.21(-0.24;0.67)	
	No intrusiveness (M) EAS	V	~11	38	0.78	0.16	37	0.73	0.23	0.25(-0.20;0.71)	
	Responsiveness (C) EAS	V	~11	38	0.70	0.13	37	0.67	0.20	0.18(-0.28;0.63)	
	Involvement (C) EAS	V	~11	38	0.69	0.14	37	0.66	0.19	0.18(-0.27;0.63)	
van den Boom et al. 1994[49]	Interactive behavior (M) (in-house)	V	9	~47			~47			1.78(1.30;2.26)	
	Interactive behavior (C) (in-house)	V	9	~47			~48			1.54(1.08;2.00)	
Velderman et al. 2006[51]	Sensitivity (M) Ainsworth's rating scale	V	11-13	54			27			0.48(0.02;0.95) ◇	
Sierau et al. 2015[55]	Affectivity (D) MBRS-R	V	24	146	3.16	0.61	142	3.35	0.63	-0.31(-0.54; -0.07)	
	Responsiveness (D) MBRS-R	V	24	145	3.38	0.70	140	3.54	0.68	-0.23(-0.46;0.00)	
Taylor et al. 1997[42]	NCATS	V	~15	50	59.5	6.1	50	59.4	6.0	0.00(-0.39;0.39) ▲	
SF	Parent-child relationship										
Høivik et al. 2005[45]	EAS○	V	~15-16	63	153.40	22.33	47	156.15	19.25	0.13(-0.25;0.51)	
MF	Parent-child relationship										
van den Boom et al. 1995[50]	Acceptance (M) Based on Ainsworth	V	18	43	6.86	1.19	39	5.95	1.88	0.58(0.14;1.03)	F=7.04
	Accessibility (M) Based on Ainsworth	V	18	43	6.88	1.50	39	5.87	1.89	0.60(0.15;1.04)	F=7.26
	Cooperation (M) Based on Ainsworth	V	18	43	6.70	1.68	39	5.18	1.65	0.91(0.46;1.37)	F=16.92
	Sensitivity (M) Based on Ainsworth	V	18	43	6.70	1.42	39	5.26	1.92	0.86(0.41;1.31)	F=15.14
LF	Parent-child relationship										

Study	Measure	Assessment	Child age (months)	Intervention				Control				Cohen's d	Other statistics
				n	Mean	SD		n	Mean	SD			
Salomonsson et al 2015b[54]	Sensitivity (M) EAS	V	54	33	0.68	0.12		33	0.67	0.16		0.07(-0.41;0.55)	
	Structuring (M) EAS	V	54	33	0.66	0.12		33	0.69	0.13		-0.24(-0.72;0.24)	
	No Intrusiveness (M) EAS	V	54	33	0.82	0.12		33	0.81	0.14		0.08(-0.406;0.56)	
	Responsiveness (C) EAS	V	54	33	0.69	0.19		33	0.74	0.15		-0.29(-0.78;0.19)	
	Involvement (C) EAS	V	54	33	0.67	0.13		33	0.72	0.16		-0.34(-0.83;0.14)	
PI	Attachment												
Cassidy et al. 2011[44]	Attachment SSP	V	12	85				84				0.30(-0.06;0.66) Δ	B=0.54 (SE=0.33) OR=1.72(0.90;3.28) \square
Velderman et al. 2006[51]	Attachment SSP	V	13	54				27				0.22(-0.22;0.66)	
SF	Attachment												
van den Boom et al. 1994[49]	Attachment SSP	V	12	50				50				0.97(0.48;1.45) Δ	Secure/insecure: Intervention: 31/19, control: 11/39. OR= 5.78 (2.40;13.94) . $L^2(1)=16.96$
MF	Attachment												
van den Boom et al. 1995[50]	Attachment SSP	V	18	43				39				1.07(0.58;1.57) Δ	$\chi^2=18.35$
LF	Attachment												
Salomonsson et al 2015a[53]	Secure Attachment SSAP	V	54	31	2.22	1.05		30	2.32	1.33		-0.08(-0.59;0.42)	
	Avoidant Attachment SSAP \diamond	V	54	31	1.05	0.48		30	1.16	0.52		0.22(-0.28;0.72)	
	Ambivalent Attachment SSAP \diamond	V	54	31	0.96	0.73		30	0.84	0.61		-0.18(-0.68;0.32)	
	Disorganized Attachment SSAP \diamond	V	54	31	0.80	0.84		30	0.63	0.58		-0.23(-0.74;0.27)	

Δ Calculation based on dichotomous outcome
 \diamond Reverse scoring – high score is negative
 \diamond Adjusted for pretest sensitivity
 \square Adjusted for income, infant sex and irritability
 Δ No control group. Two interventions were compared.
U, unadjusted; Q, questionnaire; O, observation; V, video; M, mother; C, child; PI, post-intervention; SF, short-term follow-up (≤ 6 months post intervention); MF, mid-term follow-up (7-12 months); LF, long-term follow-up (>12 months post-intervention); SMIS: Scales of Mother-Infant Interactional System; CARE: Child-Adult Relationship Experimental; EAS: Emotional Availability Scales; NCATS: Nursing Child Assessment Teaching Scale; SSP: Strange Situation Procedure; SSAP: Story Stem Assessment Profile

Meta-analysis of the primary outcome is reported in figure 3, secondary outcomes in online figures.

Figure 3 about here

Parent–child relationship

The meta-analysis of the overall parent–child relationship included nine studies and is presented in figure 3.[43,45,47,49,51,54–56,59] The parent–child relationship was significantly better in the intervention group as compared to the control group ($d=0.44$; 95% CI: 0.09 to 0.80). The measures reported in the studies vary to some degree, which could be a source of heterogeneity. I^2 was 81, indicating that a large proportion of the observed variance in effect sizes may be attributable to heterogeneity rather than to sampling error.

Maternal sensitivity

We performed a separate meta-analysis on maternal sensitivity, which is a central component in the parent–child relationship. The meta-analysis included five studies (online figure 5) and showed a significant effect favoring the intervention group ($d=0.46$; 95% CI: 0.26 to 0.65).[47,51,54,56,59]

Attachment

Two studies reported attachment classification.[44,51] They found no significant effects of the intervention.

Parent–child relationship at follow-up

Because few studies reported parent–child relationship outcomes at follow-up, we could not conduct meta-analyses for any parent–child relationship follow-up outcomes.

At short-term follow-up, one study found no significant effect on the parent–child relationship.[45] At medium-term follow-up, one study found significant positive effects on maternal acceptance ($d=0.58$; 95% CI: 0.14 to 1.03), accessibility ($d=0.60$; 95% CI: 0.15 to 1.04), and cooperation ($d=0.91$; 95% CI: 0.46 to 1.37).[50] At long-term follow-up, one study did not find a significant effect on the parent–child relationship.[54]

Maternal sensitivity

At medium-term follow-up, one study found a significant positive effect on maternal sensitivity ($d=0.86$; 95% CI: 0.41 to 1.31).[50] At long-term follow-up, one study found no significant effect on maternal sensitivity.[54]

Attachment

At short- and medium-term follow-up, one study found a significant positive effect on attachment at both the 12-month follow-up ($d=0.97$; 95% CI: 0.48 to 1.45) and the 18-month follow-up ($d=1.07$; 95% CI: 0.58 to 1.57).[49,50] At long-term follow up, one study did not find a significant effect on attachment.[53]

Sensitivity analyses

The meta-analysis on the parent–child relationship indicated that substantial heterogeneity may be present. Sensitivity analyses showed that one study in particular contributed to the high I^2 -value.[49] When this study was removed from

the analysis, I^2 decreased from 81 to 46. Tau^2 decreased from 0.19 (95% CI: 0.00 to 0.66) to 0.04 (95% CI: 0.00 to 0.19). The effect size decreased to 0.26 (95% CI: 0.05 to 0.50).

Two of the studies included in the meta-analyses had outcomes with domains at moderate to high risk of bias.[45,47] Removing Bridgeman et al. (1981) from the meta-analysis on child behavior did not alter the results considerably ($d=0.12$; 95% CI: 0.01 to 0.25). When removed from the analysis on cognitive development, the effect decreased but remained insignificant ($d=0.03$; 95% CI: -0.03 to 0.21). For the parent-child relationship the effect was almost unchanged when Bridgeman et al. (1981) and Høivik et al. (2015) were removed, but the confidence interval widened ($d=0.47$; 95% CI: 0.00 to 0.95). The effect on maternal sensitivity ($d=0.44$; 95% CI: 0.22 to 0.65) was not altered considerably by removing Bridgeman et al. (1981).

Relative effects

One study compared two active interventions: group and individual.[42] The authors found no difference between the two interventions on cognitive development, psychomotor development, or the parent-child relationship.

DISCUSSION

We identified 19 papers representing 16 trials that investigated the effects of parenting interventions delivered to at-risk parents of infants aged 0–12 months. Due to the variety of outcome measures applied, not all of the 16 included studies were included in the meta-analyses. At post-intervention, we found a small but significant positive effect on overall child behavior, but no significant effects on child cognitive behavior or the child behavior subscales internalizing or externalizing. We found a

medium-sized effect on overall parent–child relationship and maternal sensitivity. Most of the findings from studies that were not represented in the meta-analyses were not statistically significant.

The meta-analyses showed the most pronounced effect sizes for parent–child interaction and maternal sensitivity, whereas the effects on child behavior and cognitive development were either small or not significant, however, small effect sizes can have meaningful impact on population-level outcomes.[61] The non-significant outcomes for internalizing and externalizing behaviors were also small, but may be clinically relevant for large, at-risk populations. Most interventions provided direct support for how to improve maternal sensitivity and the relationship between parent and child (e.g., Circle of Security [62] and VIPP [63]). Therefore, it seems reasonable that the parent–child relationship and maternal sensitivity can be improved within a relatively short time period, whereas the effects of the interventions on child development may take longer to emerge.[64]

The tests for the child behavior subscales internalizing and externalizing narrowly included the zero value within in the 95% CIs (-0.03 to 0.33 and 0.00 to 0.30, respectively). These values suggest that similar studies to those in this review would likely produce small but positive effects. Because these analyses are based on three studies, there is a certain degree of uncertainty regarding the CIs reported. A larger sample of studies may be necessary to conclusively determine the significance of these results.

Two studies represented in the meta-analyses were assessed as having a moderate to high risk of bias in one [47] or two [45] domains. As this could potentially affect the credibility of the results, we conducted sensitivity analyses to investigate these studies' contribution to the effect sizes. However, removing these studies from the analyses did not substantially alter the effects.

The outcomes applied in the individual studies vary and most meta-analyses are based on heterogeneous measures. Although the measures vary, they do measure the same underlying construct and can therefore be meaningfully combined in the meta-analyses.

The meta-analyses of parent-child relationship and maternal sensitivity included in-house measures, that is, measures developed by the evaluators that have, to our knowledge, not been formally validated. This could potentially affect the results, however, sensitivity analyses showed that removing these outcomes from the analyses did not substantially alter the results, therefore, we kept the outcomes in the analyses.

The number of studies in the meta-analyses ranged from three to nine. While a meta-analysis on nine studies is fairly reliable, a meta-analysis including only three studies may provide a less accurate estimate of the overall effect.[65] We therefore applied the random-effects model using the profile-likelihood estimator. This has been recommended for meta-analyses with a small number of studies, because it generates wider confidence intervals than the frequently applied DerSimonian-Laird estimator.[35] The results of the meta-analyses including fewer studies should still be interpreted with some caution.

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This review focuses on interventions for adult mothers; studies with young mothers were excluded, including central studies such as the Olds studies of Nurse Family Partnership (NFP).[64] Although teen mothers are an at-risk group due to their age, and they often face additional risk factors such as poverty, low education, and single parenthood, we have not included them in this review. We believe this is the appropriate method because teen mothers are a distinct group requiring targeted care that is developmentally appropriate for their stage in life. We consider the narrower focus on adult mothers to be a strength, because the interventions aimed at adult mothers most often differ considerably from interventions for teen mothers; this specificity reduces heterogeneity in study outcomes that are often present between the teen and adult interventions.

The included studies were conducted in countries with different levels of service for families with infants; therefore, it may not be possible to reproduce effects in other contexts. The interventions examined in the studies also varied according to approach, intensity, and duration. Both short and extensive interventions were included in all meta-analyses, and we found no apparent tendencies in the results. Due to the relatively low number of studies in the meta-analyses, we could not conduct subgroup analyses. Subgroup analyses are important as they provide information about whether the effect of an intervention is modified by certain circumstances or characteristics of the participants. Eight of the included studies reported some kind of subgroup or moderator analyses.[44–49,51,56]

Most of the studies did not address implementation in their design. This presents challenges with regard to assessing outcomes, as results may have been moderated, both positively and negatively, by implementation quality. Of the 16 studies

reviewed, four provided information about efforts to support implementation, such as strategies to reduce participant attrition,[46] information about variability in the number of intervention sessions that some families received,[43,46,55] and information on the intervention.[49,50,55] All of the studies could have included more information about the implementation context and the possible moderating factors associated with different strategies. Without more extensive implementation information, replicability remains problematic, particularly in circumstances where implementation supports were not well documented.

A further limitation of the study is that although many studies reported outcomes during the intervention period and post-intervention, only a few reported follow-up data. We were able to perform meta-analysis for one long-term outcome: child behavior measured by the SDQ. The analysis included three studies and found no significant difference between intervention and control groups. Individual study results at different follow-up times were mixed and therefore inconclusive for both child development and the parent–child relationship at long-term follow-up. It is problematic that the studies did not assess long-term outcomes, because it makes it impossible to evaluate the short-, medium-, and long-term effects of the interventions. Conclusions based on post-intervention assessments may be insufficient to draw firm conclusions about the effectiveness of parenting interventions.

CONCLUSION

This review identified 16 studies that evaluated the effects of parenting interventions for at-risk caregivers with infants aged 0–12 months on child development and

parent–child relationship. Meta-analyses revealed a small but statistically significant positive effect of the interventions on child behavior as well as moderate effects on the parent–child relationship and maternal sensitivity. There were no statistically significant effects on child cognitive development, internalizing behavior, or externalizing behavior at post-intervention; however, internalizing and externalizing behavior were marginally significant and may have reached statistical significance with a larger sample. Similarly, the effect on child behavior at long-term follow-up was not significant, but approaching statistical significance. Parenting interventions initiated in the child’s first year of life appear to have the potential to improve child behavior and the parent–child relationship post-intervention.

Few studies assessed child development and parent-child relationship outcomes at follow-up; therefore, it remains unclear whether parenting interventions delivered in this population will have lasting effects. Future studies should incorporate follow-up assessments to examine the long-term effects of early interventions for at-risk families.

ACKNOWLEDGEMENTS

The authors would like to acknowledge and thank information specialist Anne-Marie Klint Jørgensen and Bjørn Christian Viinholt Nielsen for running the database searches, Rikke Eline Wendt for being involved in the review process, Therese Lucia Friis, Line Møller Pedersen and Louise Scheel Hjorth Thomsen for conducting the screening, and senior researcher Trine Filges and researcher Jens Dietrichson for statistical advice.

CONTRIBUTERS

Signe Boe Rayce co-led the review process, contributed to study design, screening, data extraction, data synthesis, performed risk of bias judgement and meta-analysis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Ida Scheel Rasmussen contributed to study design, contributed to screening, data extraction, data synthesis, performed risk of bias, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

Sihu Klest and Joshua Patras contributed to study design, data synthesis, critically revised the manuscript, and approved the final manuscript as submitted.

Maiken Pontoppidan conceptualized and designed the study, co-led the review process, contributed to screening, data extraction, and data synthesis, drafted the first manuscript, critically revised the manuscript, and approved the final manuscript as submitted.

COMPETING INTERESTS: The authors state that they have no conflicting interests.

FUNDING: Signe Boe Rayce and Ida Scheel Rasmussen were supported by a grant from the Danish Ministry of Social Affairs and the Interior. Maiken Pontoppidan was supported by the Danish Ministry of Social Affairs and the Interior and grant number 7-12-0195 from TrygFonden.

FINANCIAL DISCLOSURE: The authors have no financial relationships relevant to this article to disclose.

DATA SHARING STATEMENT: No additional data are available

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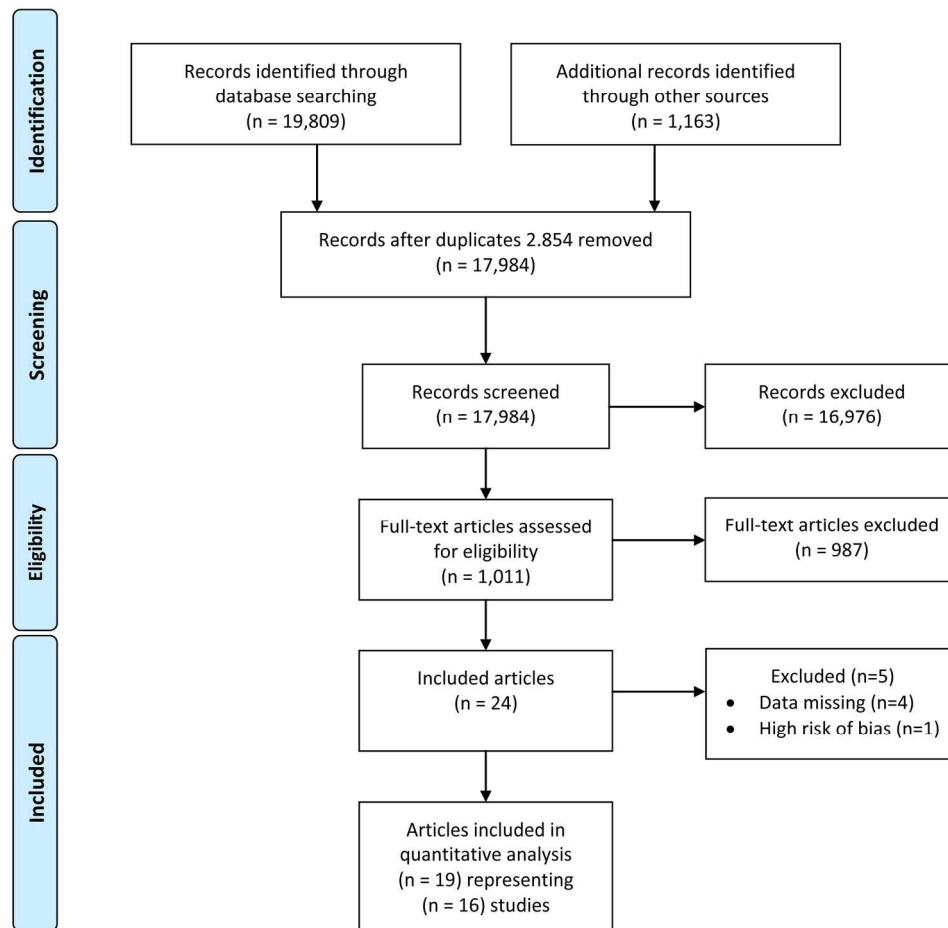


Figure 1 Flow diagram for study selection process

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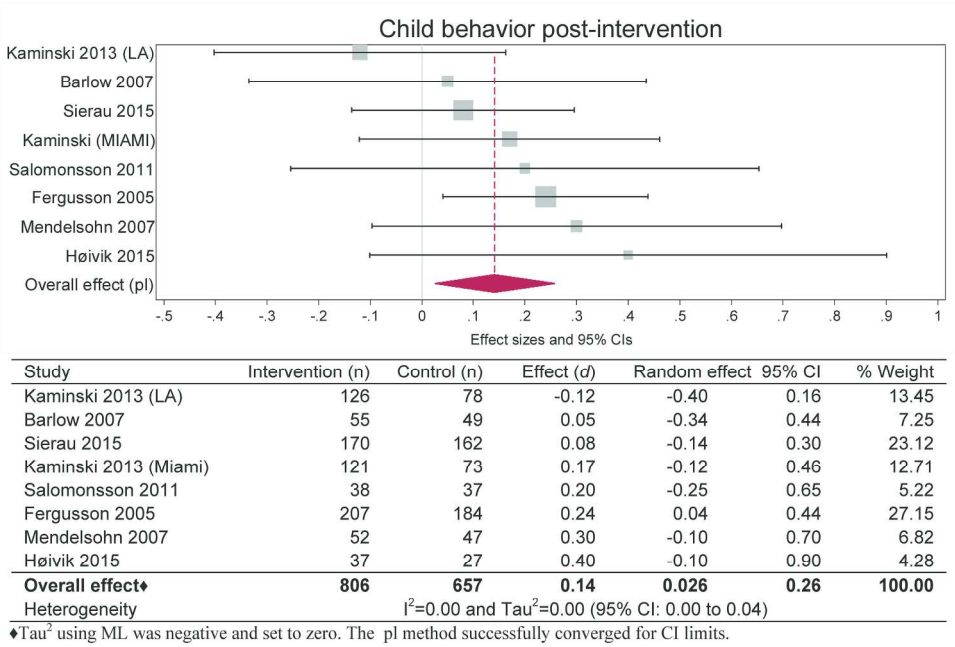


Figure 2 Meta-analysis of studies reporting child behavior outcomes at post-intervention

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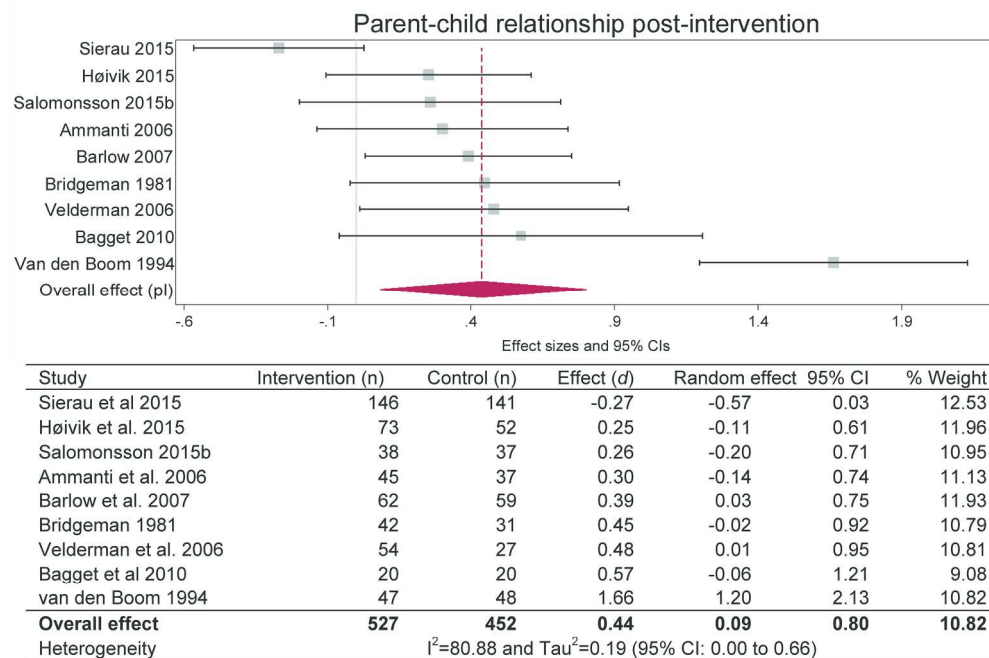


Figure 3 Meta-analysis of studies reporting parent-child relationship outcomes at post-intervention

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Online Table 1 Risk of Bias of included studies for child development and parent-child relationship outcomes

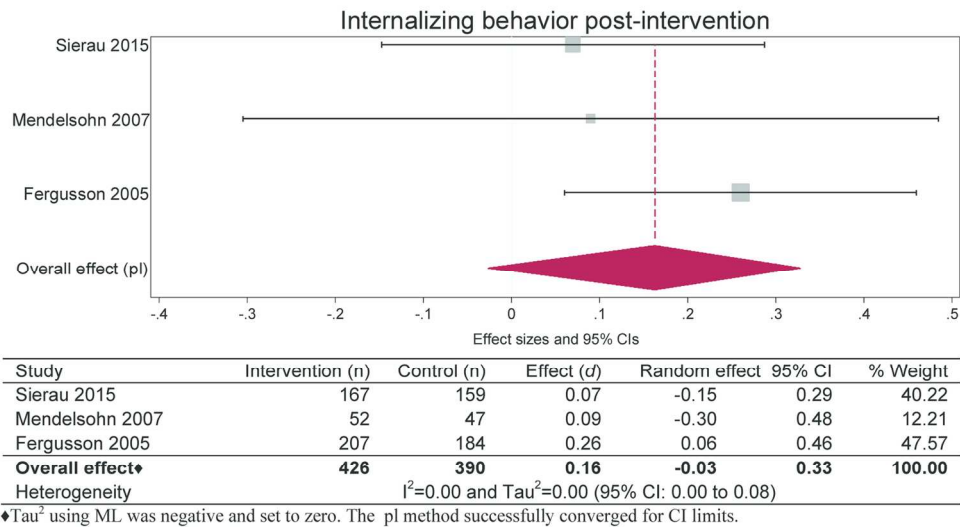
		Sequence generation	Allocation concealment	Blinding of outcome assessor	Incomplete outcome data	Free of selective reporting	A priori protocol	Free of other bias
	Outcome measures /Risk of bias domains							
Child development								
Barlow et al. 2006		L	L	-	-	-	U	-
	BITSEA/ Competence/Problems (Child behavior)	-	-	3	1	U	-	3
	BSID-II (Child cognitive and psychomotor development) BRS (Child behavior)	-	-	2	1	U	-	3
Bridgeman 1981		U	U	-	-	-	U	-
	Stanford-Binet (Child cognitive development) CFI (Child cognitive development) Pacific (Child cognitive development) Ammons (Child Communication/language development)	-	-	1	4	U	-	U
Kaminski et al. 2013*	DECA (Child behavior) SDQ (Child behavior)	L	L	3	3	1	Yes	1
Katz et al. 2011	BSID-II (Child cognitive and psychomotor development) BRS Bayley-II (Child behavior)	L	U	U	4	U	U	3
Mendelsohn et al. 2007		L	L	-	-	-	U	-
	BSID-II/MDI (Child cognitive development) PLS-3 (Child Communication/language development)	-	-	1	3	U	-	1
	CBCL/Internalizing/Externalizing/total (Child behavior)	-	-	3	3	U	-	1
Taylor et al. 1997	BSID II (Child cognitive and psychomotor development) CBCL (Child behavior)	L	U	1	3	U	U	1
		-	-	3	2	1	-	1
Fergusson et al. 2005	ITSEA/Externalizing/Internalizing/Total (Child behavior)	L	U	3	2	U	U	2
Fergusson et al. 2013		L	U	-	-	-	U	-
	SDQ (Child behavior - parent-rated)	-	-	3	2	U	-	2
	SDQ (Child behavior – teacher-rated)	-	-	2	2	U	-	2
Høivik et al. 2015	ASQ:SE (Child behavior)	H	H	3	4	1	Yes	U
Salomonsson et al 2011	ASQ:SE (Child behavior)	L	L	3	1	U	U	U
Salomonsson et al 2015a		L	L	-	-	-	U	-
	ASQ:SE (Child behavior) SDQ (Child behavior – parent-reported)	-	-	3	1	U	-	U
	SDQ (Child behavior – teacher-reported)	-	-	2	1	U	-	U
	CGAS (Child behavior)	-	-	1	1	U	-	U
Sierau et al. 2015		L	U	-	-	-	U	-
	BSID II/MDI/PDI (Child cognitive and psychomotor development) BRS Bayley-II (Child behavior) SETK-2 (Child Communication/language)	-	-	1	3	U	-	1
	ELFRA 1 and 2 (Child Communication/language) CBCL/Internalizing/Externalizing (Child behavior)	-	-	3	3	U	-	1

		Sequence generation	Allocation concealment	Blinding of outcome assessor	Incomplete outcome data addressed	Free of selective reporting	A priori protocol	Free of other bias
	Outcome measures /Risk of bias domains							
Parent-child relationship								
Ammaniti et al. 2006	Scales of Mother-Infant Interactional Systems (Parent-child relationship)	U	U	1	U	U	U	1
Bagget et al. 2010	Landry (Parent-child relationship)	U	U	1	1	U	U	1
Barlow et al. 2006	CARE-Index/ Maternal sensitivity/Infant cooperativeness (Parent-child relationship, maternal sensitivity)	L	L	2	1	U	U	3
Bridgeman 1981*	Mother-child relationship (based on Ainsworth) (Parent-child relationship)	U	U	1	4	U	U	U
Cassidy et al. 2013	SSP (Mother-Infant attachment)	U	U	1	1	U	Yes	1
Velderman et al 2006*	Maternal sensitivity (Ainsworth) (Maternal sensitivity) SSP (Mother-Infant attachment)	U	U	1	1	U	U	3
Taylor et al. 1997	NCATS (Parent-child relationship)	L	U	1	3	U	U	1
van den Boom 1994*	Maternal interactive behavior (Parent-child relationship) Infant interactive behavior (Parent-child relationship) SSP (Mother-Infant attachment)	U	U	1	U	U	U	1
van den Boom 1995*	SSP (Mother-Infant attachment) Mother-child interaction (based on Ainsworth)(Parent-child relationship, maternal sensitivity)	U	U	1	2	1	U	1
Høivik et al. 2015	EAS (Parent-child relationship)	H	H	1	2	1	Yes	U
Salomonsson et al 2015b		L	L	-	-	-	U	-
	SSAP (Mother-Infant attachment)	-	-	1	1	U	-	U
	EAS (Parent-child relationship)	-	-	1	U	U	-	2
Sierau et al. 2015	MBRS revised/Affectivity/Responsiveness (Parent-child relationship)	L	U	1	3	U	U	1

*Note: Risk of bias was conducted for each outcome. When risk of bias was the same for all included outcomes, only one score is provided in the table.

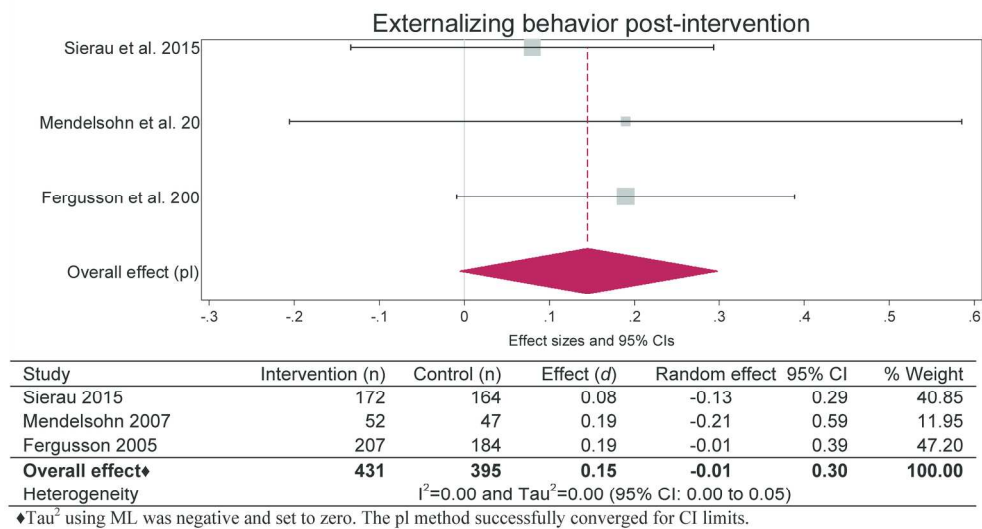
Note: In the 5-point scale 1 corresponds to low risk of bias and 5 correspond to high risk of bias. L= low risk of bias; H=high risk of bias; U= unclear risk of bias

Ammons: Ammons full range picture vocabulary test, ASQ:SE: Ages and Stages Questionnaires: Social Emotional, BITSEA: Brief Infant Toddler social and emotional assessment, BRS Bayley-II: Behavior Rating Scale, BSID-II: Bayley Scales of Infant Development, CBCL: Child Behavior Checklist, CFI: Concept Familiarity Index, CGAS: Children's Global Assessment Scale, DECA: The Devereux Early Childhood Assessment, EAS: Emotional availability scales, ELFRA 1 and 2: Elternfragebögen für die Früherkennung von Risikokindern, ITSEA: Infant Toddler social and emotional assessment, Landry: The Landry Parent-Child Interaction Scales, MBRS revised: Maternal behavior rating scale, NCATS: The nursing child assessment teaching scale, Pacific: Meyers Pacific Test Series, PLS-3: Preschool language scale-3, SDQ: Strengths and Difficulties Questionnaire, SETK-2: Sprachentwicklungstest für zweijährige Kinder, SSAP: Story Stem Assessment Profile, SSP: Strange situation procedure, Stanford-Binet: Stanford-Binet Intelligence Scales



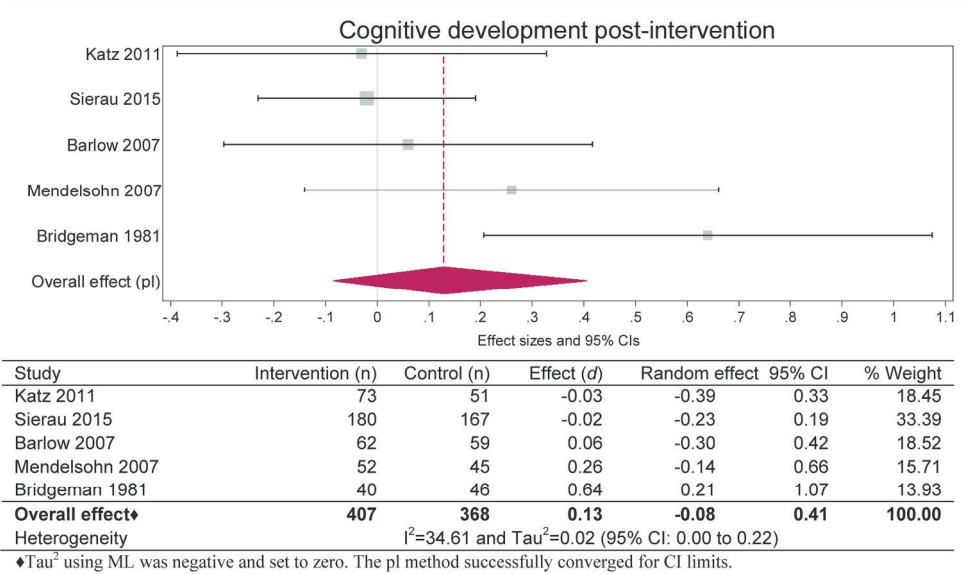
Online figure 1 Meta-analysis of studies reporting internalizing behavior at post-intervention

72x41mm (600 x 600 DPI)



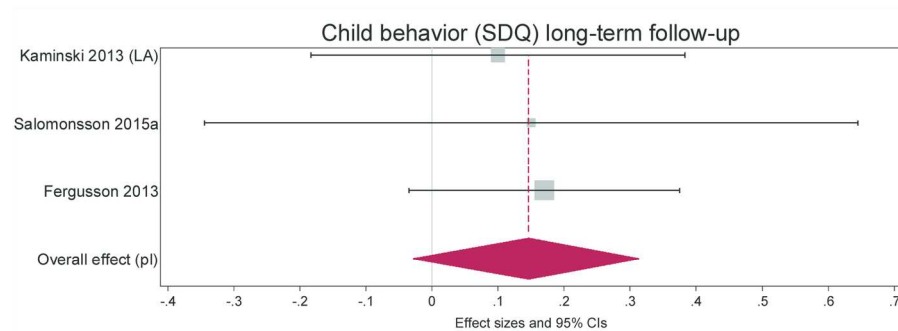
Online figure 2 Meta-analysis of studies reporting externalizing behavior at post-intervention

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Online figure 3 Meta-analysis of studies reporting cognitive development outcomes at post-intervention

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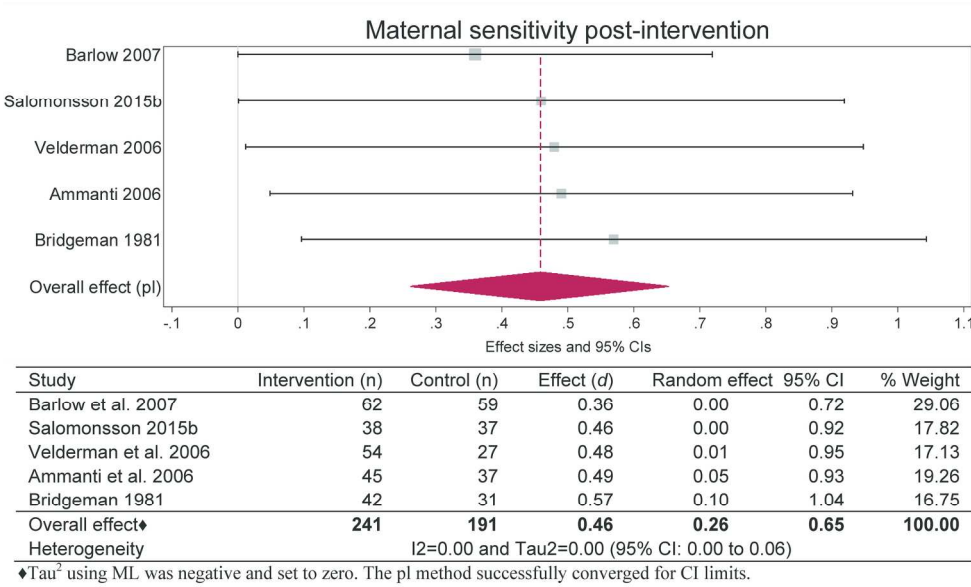


Study	Intervention (n)	Control (n)	Effect (d)	Random effect	95% CI	% Weight
Kaminski 2013 (LA)	124	78	0.10	-0.18	0.38	30.81
Salomonsson 2015a	32	31	0.15	-0.35	0.65	10.11
Fergusson 2013	199	171	0.17	-0.04	0.38	59.08
Overall effect*	355	280	0.15	-0.03	0.31	100.00
Heterogeneity	$I^2=0.00$ and $\text{Tau}^2=0.00$ (95% CI: 0.00 to 0.06)					

*Tau² using ML was negative and set to zero. The pl method successfully converged for CI limits.

Online figure 4 Meta-analysis of studies reporting child behavior outcomes at long-term follow up

76x43mm (600 x 600 DPI)



Online figure 5 Meta-analysis of studies reporting maternal sensitivity outcomes at post-intervention

92x56mm (600 x 600 DPI)